

## UNITED STATES DEPARTMENT OF AGRICULTURE

## FOOD SAFETY AND INSPECTION SERVICE

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ADDRESSING SAMPLING AND TESTING  
METHODOLOGIES, COMPLIANCE GUIDELINES  
AND N-60 LABELING

+ + + + +

October 15, 2008

8:30 a.m.

L'Enfant Plaza Hotel  
Ballroom D  
480 L'Enfant Plaza, S.W.  
Washington, D.C.

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## 1 P-R-O-C-E-E-D-I-N-G-S

2 (9:08 a.m.)

3 MR. ALMANZA: Okay. This morning we're  
4 going to get started with some examples of short-  
5 term solutions on issues that were presented  
6 yesterday afternoon, and our first presenter is  
7 going to be Dr. Karlease Kelly. She's the Assistant  
8 Administrator in the Office of Outreach, Employee  
9 Education and Training. She's responsible for  
10 Agency-wide efforts to develop the skills and  
11 scientific knowledge of the workforce as well as  
12 conducting outreach activities for small and very  
13 small meat and poultry and egg processors, to help  
14 them enhance their food safety and food defense  
15 systems.

16 Dr. Kelly has over 13 years of Government  
17 service in USDA. Her experience includes working as  
18 an instructor, a program analyst, Chief of the  
19 Program Analysis Branch of the technical service  
20 center, and more recently the Agent's chief training  
21 officer, and she's a cousin to Colt McCoy, the  
22 number one team in the college rankings. So with

1 that, I know there's some -- in the room but, hey,  
2 everybody's got to have their time. Karlease.

3 DR. KELLY: Thank you. Good morning,  
4 everyone. I know I don't look like Colt, but I  
5 really am his cousin.

6 Today we'll talk about our training program  
7 that we have for FSIS employees on *E. coli* O157:H7  
8 sampling. And we'll also talk about our outreach to  
9 small and very small plants.

10 So we'll start with employee training, and  
11 I'm very much looking forward to the dialogue and  
12 questions and feedback following this.

13 We actually do classroom training for the  
14 consumer safety inspectors and the veterinarians who  
15 collect the *E. coli* O157:H7, and they in the  
16 classroom, employees receive training on all of our  
17 sampling programs including the raw ground beef  
18 sampling, beef manufacturing trimmings, follow-up  
19 sampling after positive testing results, and testing  
20 components other than trim and imported raw ground  
21 beef. But today I think because we have been  
22 interested in talking about the N-60 method, we're

1 going to focus on that training.

2 I also want to back up and kind of give you  
3 a bigger perspective. Employees also have a much  
4 broader training background. We're not just  
5 teaching them about how to sample product. We're  
6 teaching them about the Federal Meat Inspection Act.  
7 We're teaching them about the regulations. We're  
8 teaching them about plant's processes, plant's  
9 interventions, HACCP verification, sanitation  
10 verification. So put this in context. This is just  
11 one little piece of the training that they receive,  
12 and we're just really going to kind of scratch the  
13 surface and see a few sample slides from the  
14 training that they receive.

15 Also, when they're out in the field and  
16 they're going to collect a sample, they're  
17 instructed by Notice 18-07, which is still an active  
18 and viable notice, they're instructed before they  
19 collect sampling for beef manufacturing trimmings  
20 that they must review the training CD. So that's  
21 something that we want to refresh their thinking  
22 about, remind them about how to collect the sample.

1 I'm going to share with you for the next 11  
2 slides just a few excerpts from the CD, the training  
3 CD that we have. If any of you would be interested  
4 in getting a copy of that CD, if sometime today you  
5 could give me your business card and just make a  
6 note on the back of it, that you want the employee  
7 training CD, I'll make sure that you get a copy of  
8 it so that you can have it and review the entire CD.

9 We'll just have, like I said, 11 slides out  
10 of that whole CD.

11 So, you know, first of all, this is going  
12 to give you an idea about the flow of the training.  
13 We review the sample supplies and we talk about the  
14 importance of sanitizing, you know, all of those  
15 supplies. Next we talk about the importance of a  
16 septic sampling and show them exactly some things  
17 that they can do to ensure that.

18 We also give them a lot of examples and  
19 information on how to collect the sample. We talk  
20 to them about the physical dimensions. I know we  
21 talked this yesterday, the physical dimensions for  
22 collecting the sample. We talk about the amount,



1 the 2 pounds, 60 pieces, that they are to collect.  
2 And, we also review more detailed instructions on  
3 taking the samples, taking it from the top,  
4 collecting the appropriate number, and making sure  
5 that you have 60 pieces.

6 We also give them some more detailed  
7 instructions about making sure that the samples are  
8 from the surface and that giving them again  
9 something to measure by for themselves, the thumb  
10 size from a practical point of view, that really  
11 does help people.

12 We also show them through a video, this  
13 video does not have any sound and it won't be nearly  
14 as nice as the one that Michelle's going to show you  
15 later, but we do have a very visual workforce, and  
16 sometimes showing them exactly how to do it is  
17 helpful. So I'll play this video. It's about 50  
18 seconds long showing exactly how the sample should  
19 be collected, showing how to use the sample supplies  
20 and the fact that they need to select the sample  
21 from different pieces at different locations, and  
22 how to use those supplies. Okay.

1           We also review with them how important it  
2 is that they don't cut a piece of the sample and  
3 then right underneath that cut another piece of the  
4 sample. We explain to them that any type of meat  
5 underneath the surface would be a sterile type of  
6 surface. That's not the type of sample that we  
7 want. We want the contamination that might be  
8 present on this surface. That's what we want to  
9 look at in the sample, to see if we can find any  
10 contamination that might be present. And we also  
11 encourage them not to take a sample from the same  
12 piece over and over again.

13           We talk to them about how important it is  
14 to take the temperature of the product, and if it's  
15 warmer than 40 degrees, to put it in a bag in a  
16 cooler to chill it before shipping.

17           And then we give them instructions on  
18 packing the sample. These are really important  
19 instructions, that they're not to wait until the  
20 establishment completes pre-shipment review before  
21 they submit the sample. They really need to collect  
22 it. The only intervention that they need to wait

1 for is any microbiological test results. That would  
2 be the only thing that they would need to wait for.

3           Then we also instruct them on sealing the  
4 sample properly. We have several methods, kind of a  
5 fail-safe approach to ensure that the sample is  
6 secure and that it is -- the seal isn't broken. So  
7 we give them instructions on how to do that.

8           So that's a real brief overview of what's  
9 in the training. Like I mentioned, I'd be happy to  
10 give any of you the CD if you want to review it at  
11 another time.

12           Now I'm going to talk about our outreach to  
13 small and very small plants. Some of you know that  
14 FSIS has been putting some increased emphasis on  
15 providing training and education resources to the  
16 small and very small plant operators. This is one  
17 example of some of the things that we've been doing.  
18 The small and very small plants are a very diverse  
19 audience. Those of you who are familiar with them  
20 know that there are a lot of different sizes, a lot  
21 of different ways that these people will get their  
22 information. Some of them only prefer to get it in

1 a face-to-face format. Some of them are very web  
2 savvy. Some of them would prefer to get it in a  
3 printed format. So we're trying to provide a  
4 variety of approaches to meet their needs.

5           These examples here are things that we've  
6 done on the net and in a face-to-face format. In  
7 face-to-face, we've conducted 22 sessions we call  
8 Regulatory Education Sessions. They bring  
9 inspectors and industry together to hear a common  
10 message about the regulations. We think this is a  
11 really good format to get discussion going, get  
12 people on a common ground, common understanding.

13           And some of you, how many of you have  
14 actually attended one of these sessions? I have a  
15 feeling there's some people. Yeah, there's a few  
16 people who actually attended them out in the field  
17 locations.

18           We've been to 20 states, and we've reached  
19 almost 400 people talking about these policies. The  
20 mix of the participants tend to be about 60 percent  
21 from plants and about 40 percent from inspection.

22           When we did this, our regulatory education

1 sessions, we reviewed with them the draft compliance  
2 guidelines that are posted on the web today, and  
3 I'll give you some samples of some of the things  
4 that we shared with them, and the things that the  
5 trainers have been presenting to them.

6           We also conducted two net meetings,  
7 educational net meetings. We had about 125 people  
8 present. One of those was done by Dr. Ann  
9 Hollingsworth with the Compliance Guidance that we  
10 had out and published previously. And the other was  
11 by Dr. Kerri Harris, where she talked about a  
12 variety of educational kinds of things for risk  
13 management practices, and if you're interested, you  
14 can -- to actually see what was said and hear, you  
15 know, see the slides and hear the presentation, you  
16 can go to our website and you can find those. We've  
17 recorded those here. We won't go there today but  
18 that just shows you that that information is  
19 available, not just for the people who sat in the  
20 meetings but even today, it's still there.

21           Now I'm going to show you about 12 slides  
22 of about 74 that were shared in these regulatory

1 education meetings so we can give you a sense of  
2 flavor of things that were shared in those meetings.

3           Before we talk about sampling, we do talk  
4 about just in general the importance of controlling  
5 O157:H7 and how important it is for plants, if they  
6 have prerequisite programs, to follow them and to  
7 maintain them. So we do have some preview part to  
8 this, and then we also did review the best practices  
9 that were in Notice 65-07 that many of you are  
10 familiar with.

11           Then we start to talk about microbiological  
12 testing and when we talk about this slide, the  
13 trainer talks about how, as we discussed yesterday,  
14 product testing in and of itself doesn't make  
15 products safe, but it does provide some evidence for  
16 the producer and others about the effectiveness of  
17 the process. So we're trying to help them  
18 understand, you know, why would you want to test.  
19 What are some of the benefits and how will this help  
20 you? We also talked to them about the fact that  
21 testing today is not mandated. The plant does not  
22 have to test, but we explain to them that when they

1 are producing product, and they are not testing,  
2 there's a risk. It's up to them to determine  
3 whether this is an acceptable risk, but it is  
4 something for them to consider, and maybe some of  
5 them haven't really been aware of this in the past.

6 We talk to them about how if they're going  
7 to do microbiological testing, they need to  
8 understand that O157:H7's not going to be evenly  
9 distributed through the process. It's going to be,  
10 you know, kind of in random places, and it may be  
11 very hard to find, and that's something that they  
12 have to think about when they're collecting a  
13 sample.

14 We give them some information, some basic  
15 layperson's terms, in lay terms about confidence  
16 intervals. That's kind of a complex topic for  
17 people that may be introduced to sampling for the  
18 first time, but we do explain, you know, you can do  
19 different types of sampling, and depending on how  
20 you're doing it, you will have different levels of  
21 confidence, and again, it's up to you to decide what  
22 confidence level you want for your establishment's

1 testing program. And we talk to them how it is a  
2 balance between the cost of the sampling and the  
3 risk that they run.

4 We also share this guidance that's posted  
5 on the web today about minimum sample frequencies.  
6 Again we emphasize this is guidance, but this does  
7 give them some idea about how much they should be  
8 testing, and we talk about the importance of  
9 understanding seasonality, how when the seasons  
10 change, that the prevalence increases. When the  
11 prevalence increases, testing should increase  
12 accordingly. So we explain that concept to them as  
13 well.

14 We also pose these questions for the plant  
15 to consider when they're designing a sampling plan  
16 for 0157:H7. Some of those questions would be are  
17 you using any type of intervention? What about your  
18 suppliers? What types of production processes and  
19 interventions are they using? And what about  
20 lotting? So we explain that those are things that  
21 they need to consider.

22 We also explain to them that if they have a



1 testing program for source materials and finished  
2 product, that's more effective for them than just  
3 one of those programs on their own. And we explain  
4 to them that some of the components that they may be  
5 using in their product may be riskier than others.  
6 So they should consider that as part of their  
7 sampling plan as well.

8           We talk to them about lot size. For some  
9 plants, this is another new concept in terms of how  
10 it relates to sampling. They may understand  
11 lotting, but how it relates to sampling, that's  
12 something that they need to take into consideration.  
13 We explained that, you know, lots are units of  
14 product that are grouped, and we explain the concept  
15 of affected product, if a sample tests positive and  
16 how a lot of things might go into determining what's  
17 affected, production practices, number of suppliers,  
18 the sanitation practices, and we give them some  
19 examples of common lotting sizes and some of the,  
20 you know, factors that people might consider in  
21 determining the lot size because that is their  
22 choice about how they would determine that.

1           Then we talk to the plant operators about  
2 what they should think about when they're going to  
3 select a sampling method, you know, we will  
4 eventually get to the fact that, you know, FSIS has  
5 recommended the N-60 method, but we talk about if  
6 they're sampling trim, they need to be looking on  
7 the surface. You know, the lessons learned over  
8 the, you know, past few years have told us, that if  
9 we're not looking on the surface, you know, that's  
10 not going to maximize the likelihood finding the *E.*  
11 *coli* O157:H7.

12           We also explained to them that it's really  
13 important that they randomly select samples from the  
14 product, and we recommend that they look at  
15 different times in the production process. That  
16 will help them in terms of randomizing their sample  
17 selection.

18           Then we talk about what is N-60, that we  
19 recommend N-60 for their consideration, that N-60 is  
20 not just 60 portions, but it really is supposed to  
21 represent 60 different points in the production, and  
22 that's part of what makes it a more powerful method.

1 So we talk about that in a lot more detail, skipping  
2 over a number of slides.

3           Then we talk about as we, as we mentioned  
4 yesterday, the importance of selecting the  
5 laboratory because they can do, you know, they can  
6 have great plan. They can have a great sampling  
7 program that they're implementing, but if they send  
8 it to the wrong lab, or the wrong analysis is done,  
9 this isn't, you know, this is the end of, you know,  
10 the effectiveness of the program.

11           So we talk about how important it is for  
12 them to select the right lab, that they need to look  
13 at a lab that has a validated process, and we also  
14 explained to them the concept of enrichment to  
15 detect *E. coli* O157:H7 again in very lay terms, and  
16 we give them an example. We recommend they might  
17 want to look at the FSIS testing methods guide that  
18 Emilio referred to yesterday that's on the web to  
19 get an idea about what they might be looking at.

20           Then, of course, we've got to talk about  
21 what happens if they get a positive? You know,  
22 right now, they know from a regulatory standpoint

1 what will happen, but we explained to them that the  
2 positive result represents very important  
3 information for them to look at about their process.  
4 They need to, as we talked about yesterday, they  
5 need to understand what happened. They need to look  
6 at their process. They need to make some changes in  
7 their process because this is information for them,  
8 but they also have to protect public health. We  
9 recommend that they report this to FSIS, this is  
10 highly important, and that we also recommend that  
11 they hold the product.

12           Then following this, we share with them  
13 FSIS policies and how does the Agency, how does FSIS  
14 collect the N-60 samples, so they can see some of  
15 the things that we're doing so they can understand,  
16 you know, how things are happening and how things  
17 might have an impact for them.

18           So that's a real brief summary, and if you  
19 would like, we also make a resource CD that has all  
20 the information, this presentation and a lot of  
21 other resources on it that we hand out to anybody  
22 who comes to this regulatory education meeting. If

1 you would like a copy of that CD, if you give me  
2 your business card and write on the back of it that  
3 you would like the industry CD, I'd be happy to send  
4 that to you or you can write both, and I'll send  
5 them both to you.

6           So with that really brief overview, we do  
7 have some next steps planned, and even based on  
8 yesterday's meeting, I'm getting some additional  
9 ideas, but we are constantly reinforcing our N-60  
10 training. We learn, as Emilio was saying, we learn  
11 through what happens at the laboratory, how we can  
12 do things better. So we will be reinforcing our  
13 training. We also have plans, we mentioned  
14 yesterday, how sanitation really is the foundation  
15 of, you know, what the genesis of all this is. This  
16 is the foundation, and so there is some policy  
17 development underway so that we can reinforce the  
18 importance of sanitary dressing policies, and I can  
19 assure you when that comes out, that we will not  
20 only train the workforce reinforcing that, but we'll  
21 also share that in the regulatory education sessions  
22 that we do with the slaughter operators.

1           And Emilio mentioned yesterday that we may  
2 have some new tools, we may have some new methods.  
3 So at anytime that we make some changes, then we're  
4 going, you know, train the workforce on that, and  
5 we'll also share that in reg ed sessions about the  
6 changes that we've made.

7           What about for our outreach to small and  
8 very small plants? We will be sharing the video  
9 that you're going to see soon that Michelle shows,  
10 the BIFSCO video. I think there's some really  
11 helpful information that will encourage the small  
12 and very small plant operators to think about  
13 testing. We also when we finalize the compliance  
14 guidance that Dan talked about yesterday, that's on  
15 the web, comments are closing in mid-November, we'll  
16 print that and send it out. We're not just going to  
17 rely on the fact that it's on the web, and that will  
18 be really good, but we want to actually get it in  
19 people's hands.

20           We will be conducting some additional  
21 regulatory education sessions and some net meetings,  
22 but we also want to conduct some detailed how to,

1 hands on, a little bit longer than the regulatory  
2 education sessions, a little bit more of a how to  
3 approach. So those are the things that we have  
4 planned for next steps.

5 I don't know if you're taking questions now  
6 or --

7 MR. ALMANZA: No.

8 DR. KELLY: Yeah, we're going to wait until  
9 after we get the presentation from Michelle. Thank  
10 you.

11 (Applause.)

12 DR. ENGELJOHN: Thank you, Karlease, and  
13 now I'm going to ask Michelle Rossman to come  
14 forward and make a presentation. Michelle is the  
15 Director of Beef Safety for the National Cattlemen's  
16 Beef Association. She directs a research program  
17 that includes pre and post-harvest research and  
18 dissemination and -- from BIFSCO. She has a  
19 Master's of Science Degree in Meat Science from  
20 Colorado State University.

21 Michelle, thank you for being here today  
22 and making a presentation of what you and the

1 industry has done to put together to help industry  
2 on these issues.

3 MS. ROSSMAN: Good morning. I was asked to  
4 speak this morning regarding N-60 sampling and  
5 training, but I would be remiss to focus on one tool  
6 that we have that encompasses the incredible amount  
7 of information and training that we have that really  
8 illustrates the beef industry's commitment to  
9 safety.

10 When I found this text from the HACCP final  
11 rule, it amazed me how it really does fit, how the  
12 beef industry has addressed beef safety challenges.  
13 Those in control of each segment of the farm to  
14 table continuum bear responsibility for identifying  
15 and preventing or reducing food safety hazards.

16 We have multiple programs in place that  
17 really do look at the entire continuum from farm to  
18 table, and I'll be sharing all that information with  
19 you this morning.

20 As I go through these programs, they really  
21 fit into three different categories. Research with  
22 data collection and review, technology development



1 in collaborative projects, knowledge transfer.  
2 Obviously all of that data and information that we  
3 collect would be useless to the industry and  
4 wouldn't have any effect unless we get into the  
5 hands of the right people for application. And then  
6 system implementation through the Beef Industry Food  
7 Safety Council.

8           So I'll begin with a very brief overview of  
9 research. In the early nineties, when *E. coli*  
10 O157:H7 showed itself as a challenge to the safety  
11 of U.S. beef products, we really had to get a focus.  
12 With limited resources, where could we immediately  
13 have an impact in addressing this challenge? And  
14 when you look at this diagram of the industry, it  
15 really makes a lot of sense to focus on the midpart  
16 of this continuum or the packing, processing  
17 sectors.

18           In this sector, we have approximately 35  
19 plants who harvest 95 percent of the animals in this  
20 country. So it made a lot of sense to begin  
21 focusing on this area of the continuum. This is a  
22 very busy slide, but to begin with, I'd like you to

1 focus on the yellow text. This is a list of all of  
2 the interventions that were developed through Beef  
3 Check Off funded research and other research and  
4 implemented by industry.

5           Across the country today, many of these  
6 interventions are in place in processing plants. We  
7 evaluated them through research, and they've been  
8 applied through an incredible commitment by industry  
9 to apply these interventions, and it's an ongoing  
10 commitment. These are in place and very effective  
11 in plants today, but we must continue to look for  
12 new tools that we can use in the processing of beef  
13 cattle.

14           All of these tools are applied today in  
15 what's called a multiple hurdle technology approach,  
16 and I'm sure many of you are familiar with this  
17 approach. We stack these interventions sequentially  
18 in processing plants to ensure that we have multiple  
19 opportunities to reduce any possible contamination  
20 on those carcasses.

21           After successful implementation of those  
22 processing interventions, we really needed to take a

1 look at where do we move beyond processing, and it  
2 made a lot sense to step back in the farm to table  
3 continuum and take a look at pre-harvest. We know  
4 that carcasses are basically sterile. So where does  
5 that contamination come from on carcasses? And  
6 through initial pre-harvest research, it became very  
7 clear that we needed to develop tools to reduce  
8 contamination on animal hides, the colonization in  
9 cattle as well as prevalent fecal shedding, that is  
10 how contamination gets onto the hides and that is  
11 how that contamination is brought into plants. So  
12 our focus then turned to the pre-harvest arena to  
13 develop tools for producers to use to reduce  
14 colonization and shedding of *E. coli* O157:H7,  
15 therefore reducing the contamination coming into our  
16 processing plants.

17           So again on this slide, if you could focus  
18 on the yellow text, we have over the last several  
19 years really focused in the pre-harvest arena, and  
20 to begin, we needed to do a lot of basic work.  
21 There's a lot we still don't know about how *E. coli*  
22 lives in the environment across the country where

1 cattle are raised, but as we've collected  
2 information to understand seasonality and  
3 regionality of this pathogen, we have been able to  
4 develop tools that have shown to be effective in  
5 research settings, things like live animal washing,  
6 sodium chlorate which could be a feed additive or a  
7 water additive. There are multiple vaccines that  
8 are being tested today, neomycin another feed  
9 additive and direct fed microbials as feed  
10 additives.

11           Unfortunately, I can't say to you today  
12 that we have approved pre-harvest interventions. We  
13 have been diligently working with both FDA and USDA  
14 to get approval for several interventions that again  
15 have shown to be effective in research settings, but  
16 we have not yet been able to get approval from the  
17 Government to use those. So we will continue to  
18 work very hard so that we can get tools in the hands  
19 of producers and they can play a role in this farm  
20 to table safety continuum.

21           All of these interventions both pre and  
22 post-harvest are vital parts and are hurdles in beef

1 production and processing, but we have to remember  
2 that there is no silver bullet. We will continue to  
3 need to implement the multiple hurdle system. It  
4 doesn't matter how many pre-harvest tools that we  
5 get approved and are able to use, we're not going to  
6 take our eye off what's being done at processing.  
7 It will continue to be a multiple hurdle system and  
8 we need more and more tools to be used throughout  
9 that continuum to address *E. coli* O157:H7.

10           And we must also remember that these  
11 procedures absolutely cannot be applied to replace  
12 good manufacturing practices, proper chilling and  
13 cold chain management throughout the chain and at  
14 the very beginning of the process, sanitary  
15 dressing. Again, this is a systems approach and  
16 back to the presentations and conversations we had  
17 yesterday, we really do need to approach this as a  
18 system and as a process.

19           As I said, none of this information would  
20 be useful unless we transferred it into the proper  
21 hands of those who can apply the knowledge and we do  
22 this in various ways. We have a lot of printed

1 materials that are available. We also have multiple  
2 websites. If you have any interest in seeing the  
3 research that has been conducted through the Beef  
4 Check Off, the site to look at is  
5 [www.beefresearch.org](http://www.beefresearch.org). This is a site that's used by  
6 industry. We post final reports here so that  
7 industry can immediately see that data and apply  
8 that knowledge in their daily activities.

9           Now moving onto the Beef Industry Food  
10 Safety Council, BIFSCO was formed in the late 1990s  
11 as a result of ongoing challenges in relation to *E.*  
12 *coli* O157:H7, and industry leaders really saw a need  
13 to get representatives from every single sector  
14 again of that farm to table chain together in one  
15 room to talk about how we all can play a part in  
16 addressing beef safety challenges. This group is  
17 committed to developing industrywide, science-based  
18 strategies to solve our food safety problems. They  
19 address these issues by identifying, prioritizing  
20 research, and when we do that, that could then be  
21 research that is addressed through Beef Check Off  
22 dollars. It could be research addressed through

1 USDA via the Agricultural Research Service or other  
2 funding programs that they have. So there's various  
3 avenues for communicating these research needs and  
4 getting the research completed.

5 We also focus on developing programs that  
6 can be used by the industry to operate into today's  
7 business environment, and I'll speak to best  
8 practices in a minute.

9 We also work to speak with one voice as we  
10 look to regulatory and legislative solutions, to  
11 some of our challenges and industry information  
12 programs are also a key component of this group.

13 BIFSCO is primarily funded by the Beef  
14 Check Off, but we also have a membership program and  
15 we have a very diverse membership. Our members  
16 include trade associations, universities, companies  
17 representing every sector from farm to fork, so  
18 production, processing, distribution, retail and  
19 foodservice, and also allied industry, intervention  
20 suppliers and commercial laboratories all  
21 participate in the Beef Industry Food Safety  
22 Council.

1           In 2003, we held our first annual meeting,  
2 and this was in response to again ongoing challenges  
3 from *E. coli* O157:H7. And our chairman actually  
4 describes this meeting as a family meeting. We  
5 bring together industry representatives over a two-  
6 day period to sit down and talk very openly about  
7 the challenges that we have addressing food safety  
8 as well as the successes.

9           We have all decided that food safety is a  
10 non-competitive issue. We can learn from our  
11 successes, and we can learn from everyone's  
12 challenges, and it's been an incredible venue for  
13 open sharing and development of new ideas to address  
14 our safety challenges.

15           Initially, at this 2003 meeting, we saw the  
16 need to develop best practices, to really develop  
17 documents that contain all of the information that  
18 one would need to apply across a safety system and  
19 develop a document for every single segment of that  
20 farm-to-fork continuum. And these best practices  
21 were developed in 2003 and have continued to today.  
22 They are a continued improvement process. Obviously



1 there's new knowledge that we gain all the time  
2 about this pathogen and how we deal with it, and all  
3 the other safety challenges, and we continually  
4 update those documents to ensure they contain the  
5 latest knowledge and information.

6 We've recently expanded beyond our printed  
7 documents and online documents to include a video  
8 component, which I'll share with you shortly, as  
9 well as some online interactive resources.

10 These best practices I said really are a  
11 summary of information. They include information of  
12 available technologies to each sector. They  
13 actually lay out the processing steps involved in  
14 whatever particular product you're processing, what  
15 the individual steps are and the technologies and  
16 information that can be applied there, and guidance  
17 on implementation of process control steps. We  
18 talked about that a lot yesterday and again going  
19 and stressing that this really is about process  
20 control.

21 We also have references to other guidance  
22 materials. As we all know, USDA puts out a lot of

1 guidance material, and it really helps to have all  
2 of this referenced in one document so you don't need  
3 to search for all of that guidance material. They  
4 include flowcharts and what I feel is one of the  
5 strongest parts of these documents is we actually  
6 have expert contacts listed in each best practice  
7 document.

8           So individuals like Mr. Tim Biela  
9 graciously have agreed to have their name listed in  
10 those best practice documents, and if someone has a  
11 question about how to implement best practices, or a  
12 question about some of the information in that  
13 document, they can pick up the phone and call Tim  
14 and get that technical guidance that they need.

15           We fully understand that there are small  
16 and very small processors out there who do not have  
17 the technical expertise and staff on hand to  
18 implement this knowledge and work through these  
19 documents, and therefore some of our members have  
20 agreed to serve as those expert contacts and answer  
21 some of those questions.

22           This is a list of all of the current best

1 practice documents that are available, and you'll  
2 see that we start with pre-harvest and walk the  
3 whole way through the chain to retail and  
4 foodservice.

5           At the bottom of the list is actually our  
6 latest document that was produced, Best Practices  
7 for Using Microbiological Sampling, and this is a  
8 focus of this meeting, and in conjunction with that  
9 best practice document, we really saw the need to  
10 develop a visual tool. As Dr. Kelly mentioned, a  
11 lot of people are visual learners, and to read the  
12 text of how to conduct N-60 and then apply it,  
13 obviously we have great variation across people,  
14 across plants on how that is applied. So we really  
15 saw the need to develop a visual tool and a video  
16 that could be used by industry to apply N-60.

17           So as soon as this comes up, I would like  
18 to share this video in its entirety with you.

19           (Playing video.)

20           MS. ROSSMAN: This video has been well  
21 received by industry, and we certainly appreciate  
22 USDA's willingness to help us with outreach and to

1 disseminate this to small and very small plants.

2           We disseminate these best practices in  
3 various ways. The website listed at that site, all  
4 of the best practices are available free of charge  
5 and can be downloaded for use. The video can also  
6 be ordered from this site.

7           Other ways that we disseminate best  
8 practices include technical meetings. Just two  
9 weeks ago, we assisted with a meeting in Chicago  
10 where we had approximately 170 industry  
11 participants, and we reviewed many of the best  
12 practice documents and had technical experts there  
13 to assist in disseminating that information.

14           And, of course, our annual safety summit.  
15 And I need to touch on this meeting because it is  
16 such an important gathering that addresses beef  
17 safety challenges. We host this meeting annually,  
18 and our next one will be in March of 2009, and this  
19 really is again a family meeting. We have created  
20 an atmosphere for very open sharing across all  
21 industry segments. It's a time for information  
22 sharing in very small group settings, hands-on

1 training and technical sessions if you will. A lot  
2 of information is transferred in those two days.

3 We also include research updates. We bring  
4 in researchers to share with us the latest data and  
5 information that's been collected from all of the  
6 research that goes on over a 12-month period, to  
7 share with us the very latest information and then  
8 talk about how we can apply it on a daily basis.

9 We also talk about emerging issues. It's  
10 essential with all the time that we focus on *E. coli*  
11 O157:H7, that we don't take our eyes off emerging  
12 challenges, things like MRSA's, *C. difficile*, just  
13 watching the research and bringing experts in to  
14 talk to us about some of those other issues to  
15 ensure that they don't become challenges for us  
16 regarding the safety of U.S. beef products.

17 The one segment of the farm-to-fork  
18 continuum I haven't touched on is the consumer, and  
19 they are the last segment of the beef safety chain.  
20 And, through the use of Check Off dollars, we do  
21 conduct a lot of consumer education programs, and we  
22 also do outreach at retail and food service and are

1 continually conducting research in the field to get  
2 an understanding of consumers' perceptions of beef  
3 safety.

4           The websites on your left is a screen shot  
5 from beefitswhatsfordinner.org which contains a  
6 safety tab, and it has extensive information for  
7 consumers about everything the industry is doing to  
8 address beef safety.

9           The beautiful picture of the burger there  
10 on the right is part of a new program that we've  
11 just developed called safe and savory at 160  
12 degrees. We found through some consumer research  
13 that there are few consumers who understand that raw  
14 ground beef products need to be cooked to 160  
15 degrees, and we also found that many had a  
16 misperception that cooking it to 160 degrees, they'd  
17 have a bad eating experience. So we came up with  
18 this idea of safe and savory at 160. It's a safe  
19 product, and you also have a really good eating  
20 experience.

21           As I said, this is a very new program.  
22 We're looking at ways to disseminate this

1 information possibly through family programs like  
2 the YMCA and PTA across the U.S. So we continually  
3 understand that consumers also play a key role and  
4 have a responsibility in handling and cooking our  
5 products properly, and we'll continue to work with  
6 that sector to educate them.

7 I've talked about the history of some of  
8 our programs as where we are current day and want to  
9 talk a little bit about our ideas as we continue to  
10 move forward and address beef safety challenges.

11 There's still a lot we don't understand  
12 about the on-farm ecology and epidemiology of *E.*  
13 *coli* 0157:H7. Super shedders. Some of you have  
14 probably heard that term. We've done some research  
15 that shows that there are some animals in a pen who  
16 may shed incredible amounts of *E. coli* 0157:H7.  
17 What do we do about that? Why do those animals shed  
18 all of that, you know, these large volumes of  
19 pathogens? There's a lot we need to learn there.  
20 There's much we don't know about current management  
21 practices. Could feeding practices be affecting  
22 shedding of these pathogens? There's still some

1 work and some knowledge we need to gain there.

2           As I mentioned, pre-harvest interventions.  
3 We have several that are currently seeking  
4 regulatory approval but we need to continue. Once  
5 those are approved, they need to be optimized and  
6 improved, and we need to find more tools and we'll  
7 continue to focus on that.

8           Processing interventions. We need to  
9 continue to evaluate them and understand if they're  
10 optimized and also is there new technology that  
11 needs to be implemented in the processing arena and  
12 emerging issues. Again, we'll continually track  
13 those emerging issues to ensure that there aren't  
14 new challenges that we're missing.

15           We also have the need for a true process  
16 control tool, and you heard some of this discussion  
17 yesterday but we feel this is a role that BIFSCO  
18 could play in beginning this discussion of how do we  
19 develop something that's a true process control  
20 tool, and we actually have some researchers in the  
21 room who are going to share some information, a  
22 little bit, about some research that they've done.



1 But BIFSCO has done such a good job of bringing  
2 experts to the table to talk about new ideas that  
3 this is a role that we could play and begin this  
4 discussion.

5           Something else that we've been discussing  
6 is the development of a food safety objective. At  
7 this point, we do not have a true target for *E. coli*  
8 O157:H7. Zero, we would all love to eliminate the  
9 pathogen, but I think we all know that that's  
10 unattainable. So what is the true target? And  
11 that's something that we want everybody in the farm-  
12 to-form continuum to weigh in on those discussions  
13 from pre-harvest through to the consumer groups and  
14 that's something that as we move forward here that  
15 we'll be leading that discussion in the development  
16 of a food safety objective.

17           Outreach and training has to continue to be  
18 a focus. Through the annual beef safety summit, our  
19 producer leaders are committed to continually  
20 funding that. Technical workshops are needed. I  
21 had a discussion this morning with Dr. Kelly about  
22 how we could partner with some of the education and

1 training that she's doing and bring in some of our  
2 experts to continually enhance that training.

3 We'll continue to focus on best practices  
4 and add new knowledge and information there, and  
5 BIFSCO.org, we hope to turn that into one stop for  
6 beef safety information, research data, et cetera,  
7 and we'll continue to develop that website. So  
8 continually check that website for new updates.

9 In conclusion, when I look again at this  
10 text from the HACCP final rule from 1996, I begin to  
11 look at where I fit in this continuum, and it's  
12 really interesting because my husband and I actually  
13 operate a cow-calf operation in Minnesota. So I'm  
14 at the very beginning of the continuum. We start,  
15 you know, we calve baby calves every year, and we  
16 take the responsibility very seriously in following  
17 beef quality assurance techniques and animal  
18 husbandry, in ensuring that those animals are in  
19 their optimal healthy well-being at all times when  
20 they're in our care. We take that very seriously as  
21 we think about our operation possibly being a fourth  
22 generation family operation, you know, if our young

1 sons decide to follow in our footsteps and make a  
2 living in production agriculture, we want to ensure  
3 that we've been good environmental stewards and have  
4 an operation that's viable for them to take over in  
5 a few years.

6           In my job, I kind of fit in the middle of  
7 the continuum. I'm very fortunate to work with  
8 industry thought leaders who are consistently  
9 challenging and thinking about what we're currently  
10 doing on an every day basis and how we can improve  
11 that, thinking about what we need to do in research,  
12 thinking about how we train and educate to do a  
13 better job of addressing these safety challenges.

14           And I also fit at the very end of the  
15 continuum. I'm the mother of three young sons, and  
16 I fully understand my responsibilities every time I  
17 produce a meal for them and that there are things in  
18 my control that I need to properly handle and cook  
19 my food, and there are things that I can do to  
20 reduce food safety hazards.

21           So it's an interesting fit for me as I  
22 think about this continuum and my responsibility,

1 and I understand and take all of those  
2 responsibilities very seriously.

3 So I certainly appreciate your time. I  
4 look forward to further discussion of how the beef  
5 industry can continue our commitment to beef safety.  
6 Thank you.

7 (Applause.)

8 DR. ENGELJOHN: Well, thank you. At this  
9 time, are there any questions or suggestions for  
10 enhancing or improving anything that you saw this  
11 morning from the two presentations?

12 OPERATOR: If you'd like to ask a question  
13 from the phone, please press star and 1.

14 DR. ENGELJOHN: We have an individual over  
15 here. If you could give us your name and  
16 affiliation.

17 DR. ACUFF: Gary Acuff, Texas A&M  
18 University. Thanks, Michelle. I think BIFSCO, you  
19 know, has served the industry well in terms of  
20 promoting food safety, and also NCBA has funded  
21 quite a bit of research, and so I just want to  
22 briefly mention some of the things that we've done.

1 Actually this was initially funded by USDA.

2           You know, you can historically non-detect a  
3 particular indicator over a period of time, and that  
4 may indicate that your process is in control, but it  
5 also might indicate that the organism is not equally  
6 distributed, that it's stressed, that your  
7 methodology is not working well, that your sampling  
8 plan's not effective. You don't really know. You  
9 just know that you're not detecting it. Hopefully  
10 it's because your process is in control.

11           One of the things that we've been working  
12 on is trying to develop tools that we could use at  
13 specific critical control points in the process to  
14 show actually how much reduction you're getting by  
15 critical control point and thereby build it, help  
16 you come up with a sum of reductions that would help  
17 you get to a food safety objective. If we're going  
18 to have a food safety objective, you have to be able  
19 to add up your reductions to get to that point.

20           So Dr. Dickson from Iowa State and I have  
21 worked in collaboration now for several years on  
22 trying to develop a list of surrogate organisms that

1 are non-pathogenic but that represent the kill that  
2 you would get or the growth that you would get with  
3 *Salmonella* or O157:H7, and we have a group of about  
4 five or six, five, and they've now been donated to  
5 the American Type Culture Collection. So anybody  
6 can get them. You just have to contact ATCC and  
7 request those organisms, and we've used those.

8 Well, now here's the rub to the situation.  
9 Whenever I've used these in Texas for testing, I've  
10 gone into plants and convinced the inspector that I  
11 can come in and inoculate the neck prior to a CCP  
12 and then go through the process and measure at the  
13 end, see how much reduction we're getting which  
14 would indicate how much *Salmonella* or O157:H7 we're  
15 reducing. I've had luck with that. Jim, on the  
16 other hand, has been blocked by inspectors who say  
17 no, no, no, you can't come in and inoculate.

18 So there's some inconsistency there. You  
19 know, if we're going to actually validate CCPs,  
20 using a process like this, then we have to have some  
21 help from FSIS in terms of allowing us to come in  
22 and do some inoculation so that we can measure an

1 accurate reduction. And the only way we're going to  
2 come through with a validate, verifiable process is  
3 to be able to show exactly how much reduction we're  
4 getting at each point in the process, so that when  
5 we add that up the end and meet ultimately a food  
6 safety objective.

7           So is there anything you wanted to add to  
8 that, Jim?

9           DR. DICKSON: No.

10           DR. ACUFF: Okay. So I'm a better salesman  
11 than Jim, you know, with the inspectors. So --

12           DR. ENGELJOHN: Thank you, Drs. Acuff and  
13 Dickson. We appreciate that, and FSIS definitely  
14 will be getting in contact with you. We are  
15 focusing as we go forward on validation because we  
16 believe that's an area where we have to refocus.  
17 And so I think that would present some opportunities  
18 that we need to discuss. So we'll move forward.

19           We have a question up front.

20           MS. NESTOR: Felicia Nestor, Food and Water  
21 Watch. I actually have a couple of questions.

22           Karlease, I was wondering, do you keep

1 names of all the people that attend the training  
2 sessions? Because I see on your slide that you said  
3 something like 375 people in 20 states attended.

4 DR. KELLY: I don't know how to turn this  
5 on.

6 MS. NESTOR: Conducted 22 regulatory  
7 education sessions in 20 states where there were 375  
8 participants.

9 DR. KELLY: Yeah. What we do is we ask  
10 people to sign up, and very much like this meeting,  
11 some do and some don't, and then when they come to  
12 the meetings, we ask them to sign in. Right now we  
13 have a file, a paper file with a large, you know,  
14 number of all this information. It's sitting in a  
15 file. So if we need to gather that information, we  
16 can, but this year, one of our focuses is going to  
17 be on following up and finding out if after people  
18 have attended these sessions, did they actually  
19 learn something, was it actually beneficial to them?  
20 So we're going to convert that into scannable form  
21 so we can have more information.

22 But our purpose is really not to track the



1 names of the people that attend, but we could get  
2 that kind of information possibly.

3 MS. NESTOR: Well, I'm not interested  
4 necessarily in exactly who. It's just I went to the  
5 one in Newark, New Jersey, and as you know, that  
6 area of the country has the most small and very  
7 small plants, and there was one other guy there.  
8 There was a woman who sat behind me, but I think she  
9 might have been a wife of one of the presenters.  
10 I'm not sure. So if I had not been there, there  
11 would have been one person.

12 I can also say that, you know, while the  
13 presenters tried to do the best job they could,  
14 basically all they could do was read what was on the  
15 slides and couldn't answer any questions. I mean I  
16 asked some of the most common questions that people  
17 have about this, and they didn't have the answers.  
18 So I would hope that you would start to keep track  
19 of that, you know, the questions that can't be  
20 answered because obviously everybody can read what's  
21 on the PowerPoint slide.

22 DR. KELLY: We actually do collect those.

1 After every session, we get a list of the questions  
2 and we feed them back to the Policy Office so they  
3 might go into the development of future resources as  
4 well as Q&As, and we do realize, you know, as much  
5 as we try to, you know, maximize the scheduling of  
6 these sessions, there are some times when we don't  
7 publicize them as well as we should or we pick a  
8 date or a time that's not necessarily convenient for  
9 people in the area. So we're trying to do better  
10 with that.

11 DR. ENGELJOHN: I'll take one more question  
12 in here before I go to the phones, because the  
13 phones are working today, and I want to give them an  
14 opportunity.

15 MS. NESTOR: I actually had a couple of  
16 more but --

17 DR. ENGELJOHN: Could you pass it over?  
18 Yes. Thank you.

19 MS. KOWALCYK: Barb Kowalcyk, CFI. One  
20 question that I had, and it's more of a suggestion,  
21 is while the educational materials that you have are  
22 great, the one thing I found that was lacking is

1 what do they do with the data that they get back  
2 from the testing, you know, I mean the whole key to  
3 process control is in tracking the data over time,  
4 and I know you referred to a process control tool.  
5 But it is going to take a quite a bit of education  
6 to teach not only the inspectors but also the plant  
7 operators, you know, how they will use that data to  
8 effectively monitor their control.

9           And the other thing, I do have some  
10 questions and I can certainly speak to you  
11 privately, but in terms of collecting the sample,  
12 you know, do any of your programs actually define  
13 what it means to take a random sample? Most people  
14 think, you know, I just randomly pick a number out  
15 of the air. Well, everyone has an inherent bias.  
16 There's way to actually do true random sampling or  
17 to the best we ever can get there, and also you  
18 really didn't touch on stratified sampling and the  
19 role that possibly could play in developing a  
20 sampling plan.

21           DR. ENGELJOHN: Do you want to address  
22 that, Michelle?

1 MS. ROSSMAN: As far as the use of data, I  
2 will tell you that in our best practices, we do have  
3 text in there describing what they should then do  
4 with the information that they get from their  
5 testing programs, and I'd be happy -- we can walk  
6 through some of those best practice documents, and I  
7 can show you where some of that text is and how we  
8 try to educate them on what to do with the  
9 information.

10 MS. KOWALCYK: That's great, but again as  
11 you said earlier, people are very visual learners.  
12 It would be great to show them what a control chart  
13 looks like and how you would actually implement that  
14 in your daily practice of updating that and how you  
15 would actually interpret a control chart.

16 DR. ENGELJOHN: Great. Operator, are there  
17 any questions from the phone?

18 OPERATOR: At this time, I have no  
19 questions from the phone.

20 DR. ENGELJOHN: Okay.

21 MS. BUCK: This question is for Michelle.  
22 My name is Pat Buck, and I'm with the Center for

1 Foodborne Illness, Research and Prevention. And my  
2 question is about this safe and savory at 160. As  
3 an educator, and I am a teacher, I'm very interested  
4 in how we're going to get those food safety messages  
5 out to 300 million people. And what is your plan to  
6 either partner with other people within the meat and  
7 poultry industry? And what is your plan to partner  
8 with other non-profit NGOs like us or like others to  
9 convey those very important messages?

10 MS. ROSSMAN: That's a great question. As  
11 I mentioned, we have just developed this program  
12 based on consumer research that we did, and we are  
13 right now evaluating our best ways to get that  
14 message out, and I'd love to have a conversation  
15 with you later because we have put together a list  
16 of organizations who we see as targets who could  
17 help us to get that message out, and you may be the  
18 perfect partner. So I'd like to have that  
19 conversation with you.

20 MS. BUCK: Well, thank you.

21 MS. ROSSMAN: We understand it is a huge  
22 challenge --

1 MS. BUCK: Yes.

2 MS. ROSSMAN: -- and we have very limited  
3 dollars on the consumer education programs that we  
4 do. So we're always looking for ways to disseminate  
5 that information.

6 DR. ENGELJOHN: Okay. In the back. Thank  
7 you.

8 MR. CORBO: Tony Corbo, Food and Water  
9 Watch. I wanted to follow up on a comment and  
10 assertion that my colleague, Felicia Nestor, made  
11 yesterday about the, it seems to be contraction in  
12 the industry among small and very small plants and  
13 what is causing that. I know that she was  
14 criticized for using FOIA-ble information on testing  
15 data to make that assertion, but the Agency on an  
16 annual basis submits data to Congress, and I just  
17 wanted to give you the latest information I have,  
18 that between FY 2001 and FY 2006, there's been a  
19 decline in the number of small plants by 242 plants  
20 or a 10 percent reduction, and among very small  
21 plants, the reduction has been 357 plants or about  
22 11 percent.

1           Karlease, in your outreach program, have  
2 you identified what is causing that? And as  
3 contrast, the number of large plants in that same  
4 timeframe has gone up from 350 to 359. What is  
5 going on?

6           DR. KELLY: I think that is a really good  
7 question. It is something that I would like to look  
8 into. At other public meetings, we've learned that  
9 FSIS is doing more with data, and I think that's one  
10 of the things that I want to follow up on, is to  
11 find out, you know, what is happening? What is the  
12 cause? And is there something that we should be  
13 concerned about? And if so, what should we do about  
14 it?

15           So it is something I'm interested in and  
16 following up on.

17           DR. ENGELJOHN: Tony, I would just say we  
18 as an Agency will be looking into the issue of that.  
19 As Karlease said, it's an issue that we need to have  
20 a better understanding for. So we've noted that,  
21 and we'll put that on our agenda. Yes.

22           DR. HOLLINGSWORTH: Jill Hollingsworth,

1 Food Marketing Institute. We represent the retail  
2 food stores, and my question is directed to  
3 Michelle.

4 As you know, our concern for O157 is not  
5 just in the meat supply. It's also fresh fruits and  
6 vegetables, and I thought I heard you say that there  
7 were no approved pre-harvest interventions. I  
8 wanted to get that clarified, but also if you could  
9 give us some update on where is the industry with  
10 approval of the pre-harvest, the vaccines,  
11 probiotics, feed additives, because all our focus is  
12 let's get O157 out of the food chain, not just worry  
13 about getting it out of the ground beef at the point  
14 of production, but let's work on the cattle.

15 MS. ROSSMAN: There are no approved pre-  
16 harvest interventions. Right now, sodium chlorate  
17 is in front of FDA for approval, and there are two  
18 vaccines as well as another technology in front of  
19 USDA trying to gain approval. We are working with  
20 them in a coalition with other meat associations who  
21 represent all sectors of processing and production  
22 to expedite that process.



1           It's my understanding that next summer we  
2 would expect to have approval to go to the next step  
3 of approval, which would be large-scale trials in  
4 the field to get a real handle on efficacy in large  
5 trials, and then the next step would hopefully be  
6 approval.

7           I'll tell you, it's been a very long,  
8 frustrating process. It's really a new thought  
9 process applying interventions to a live animal that  
10 may have an effect on public health. So it's been a  
11 real education process, and we're not there yet.

12           I know I've been saying for many years,  
13 hopefully next year we'll have a pre-harvest  
14 intervention, but we're not there yet, but we are  
15 very actively working with USDA and FDA to get  
16 approval.

17           DR. HOLLINGSWORTH: Well, anything we can  
18 do to help that, we would like to participate.

19           DR. ENGELJOHN: This is Engeljohn. I would  
20 just say on that matter, FSIS has weighed in that in  
21 terms of those kind of pre-harvest interventions  
22 that could take effect, it's our belief that any

1 reduction is an effective tool as opposed to  
2 striving to get a significant reduction. And so  
3 there is a difference in thought process there that  
4 I think that we're all working through, and so  
5 that's one of the issues that I think that we've  
6 overcome to some extent.

7 Any other questions in the room before we  
8 move onto the next presentation?

9 (No response.)

10 DR. ENGELJOHN: Any issues or questions  
11 coming in from the phone, Operator?

12 OPERATOR: If you would like to ask a  
13 question, please press star and 1 on your touchtone  
14 phone.

15 DR. ENGELJOHN: And I'll just remind those  
16 of you that are in the room that we don't have a  
17 scheduled break, and so I would just suggest that  
18 you can get up and get your coffee or take a break  
19 as you need to, but we'll go forward with the  
20 presentation and get in public comments as well.

21 We have a question here.

22 MS. NESTOR: Felicia Nestor, Food and Water

1 Watch. First, I just wanted to say that I really  
2 appreciate the BIFSCO document on the guidelines.  
3 You know, when I was looking to make comments on the  
4 N-60, you know, the cautionary comments are in the  
5 BIFSCO document. So I thought that was really good.

6           And this question, I'm not sure if it's  
7 appropriate now or, you know, I hope it's answered  
8 sometime today by FSIS or the industry. When I was  
9 in Chicago at the industry meeting, a small  
10 processor got up and said, you know, when we find a  
11 positive, you know, we all have the responsibility  
12 to identify all of the contaminated product and get  
13 it off the market. Now, obviously that processor  
14 was under the impression that FSIS was going to be  
15 involved in that and that there is a goal of  
16 identifying through trace back and trace forward all  
17 the contaminated product, and that is not the case.  
18 And some consumers are under the impression that  
19 that's the case. At that public meeting, no one  
20 corrected the woman and said, no, we really don't  
21 try to do that.

22           And so I hope that today you make it clear

1 that that currently is not a goal of the regulatory  
2 program.

3 DR. ENGELJOHN: This is Engeljohn. I'll  
4 answer from the policy perspective of the issue for  
5 what we do today, which is for every FSIS positive  
6 or an AMS positive or other state lab positive that  
7 react to, in terms of pursue as a sample result that  
8 we're responding to, as if it were our own. There  
9 is a trace back. So that goes back to the product  
10 affected by that production lot that's represented  
11 by that sample and a determination made as to  
12 whether or not additional product is affected as  
13 well as to the supplying establishments. And that's  
14 what our STEPS database is intended to accomplish  
15 which is to go back and do a look at the production  
16 practices in place on the day on which that product  
17 was produced.

18 So from the product that's in the FSIS  
19 chain, for which a sample is represented by an FSIS  
20 equivalent sample, that does occur.

21 For the results associated with industry  
22 testing results, there presently is not a mechanism

1 in place in which the Agency follows up with the  
2 supplying establishments. When a slaughter  
3 establishment, a trim fabrication establishment or a  
4 grinding establishment or at retail finds a  
5 positive, that mechanism is not in place. It is a  
6 mechanism for which the Agency is looking into a  
7 process by which we could follow up on those  
8 positives, but that is not the case for the industry  
9 testing results. It is only the case with the FSIS  
10 ones.

11 MS. NESTOR: Okay. Just to be clear, tell  
12 me if I'm wrong. If FSIS finds a positive at a  
13 plant and the grinder identifies one single  
14 supplier, FSIS will go within several days and take  
15 some follow-up samples at the supplier, but there's  
16 no attempt to go back to the supplier that day and  
17 say Lot X was tested positive. Where else did you  
18 send all of the Lot X? Am I correct about that?

19 DR. ENGELJOHN: And the issue is when we  
20 find a positive, we identify that the production lot  
21 represented by that positive is microbiologically  
22 independent. So it's the data associated with that,

1 whatever the plants may have in terms of segregating  
2 that production lot from others. So that  
3 investigation is made, and then that makes a  
4 determination as to whether or not a recall is  
5 necessary to pull additional product out of the  
6 marketplace that may have been affected by that  
7 production sample because the lot may not have been  
8 properly identified.

9 At the same time, FSIS goes back to the  
10 supplying establishment and looks to see whether or  
11 not there's evidence on that day that the production  
12 process for which the lot was positive for would  
13 indicate that there's reason to believe other  
14 product is affected. So in that case, product  
15 moving from the supplier to the receiver would not  
16 necessarily be affected unless there's evidence that  
17 the product should be linked to it.

18 So the circumstances are that an immediate  
19 determination is made about product associated with  
20 a sampled lot.

21 MS. NESTOR: Well, I've done a FOIA, and  
22 I'll be looking at those records.

1 DR. ENGELJOHN: Okay.

2 MS. NESTOR: So we can go over it then, but  
3 if there are two suppliers, the name is put into a  
4 STEPS database, and if that plant's name comes up  
5 twice within 120 days, then the Agency goes back,  
6 right? So in the case where you have FSIS testing  
7 finds a positive with two or more suppliers, there  
8 is no immediate sampling done and no attempt to  
9 trace forward.

10 DR. ENGELJOHN: The issue related to follow  
11 up sampling is the one looking at current production  
12 practices, but in every case where there's a  
13 positive and the suppliers are identified, there's  
14 an 02 procedure back at the supplier in every case.

15 MS. NESTOR: Which means -- an 02 procedure  
16 is when FSIS goes and look at the plant records to  
17 see whether the plant noted that there was probably  
18 a problem with that production lot.

19 DR. ENGELJOHN: It looks at the production  
20 process to see if there's evidence that the  
21 production was properly processed that day.

22 MS. NESTOR: Right.

1 DR. ENGELJOHN: That is what they're  
2 rechecking and doing an investigation for.

3 MS. NESTOR: And I asked Ken Peterson at  
4 one point, when you go to the grinding plant, do you  
5 ever find that the grind plants' records indicate  
6 that there was a problem, and he says, no.

7 DR. ENGELJOHN: Okay.

8 MS. NESTOR: Okay. The records are  
9 basically not very helpful.

10 DR. ENGELJOHN: Okay. Are there other  
11 questions in the room before we go to the next  
12 presentation?

13 (No response.)

14 DR. ENGELJOHN: Okay. I'm going to give  
15 you an overview of the trim sampling compliance  
16 guidelines and the discussion following that, and  
17 we'll entertain until noontime, if there are  
18 questions that come up, related to that, or we'll  
19 move on with the agenda depending on what kind of  
20 response we get to the presentation that I make.

21 For those of you who don't know me, I am  
22 the Senior Strategic Risk Manager for the Agency.



1 It is my responsibility to look into what risk  
2 management practices we need to have in place to  
3 control public health related risks associated with  
4 the products that we regulate.

5 In the outline I'm going to give you today,  
6 we're going to go through the purpose of the  
7 guideline, the guideline's content and then next  
8 steps that I envision that the Policy Office would  
9 be pursuing with regards to this guideline. And  
10 then we'll provide an opportunity for public comment  
11 on issues related to the guidance document, things  
12 that can be done to improve it or enhance it, things  
13 that we need to consider, and then as I can, I will  
14 provide clarification to any of the issues that you  
15 might raise during the discussion.

16 The purpose of the guideline was to first  
17 of all address the adverse events which are related  
18 to *E. coli* O157:H7 in both calendar years 2007 and  
19 through today in calendar year 2008. We had  
20 identified that the controls for O157:H7 are not  
21 adequate to protect public health and that we need  
22 to put in place additional control measures to

1 reduce risk.

2           Part of those adverse related activities  
3 are associated with outbreaks for which there's  
4 human health associated with raw beef products in  
5 both years. Prior to calendar year 2007, there were  
6 no reported human-related illnesses associated with  
7 the beef products for which we had a recall. But  
8 last year there were a record number in terms of  
9 those directly associated, and then we've had some  
10 as well this year.

11           In addition, we do track the percent  
12 positive rate in the verification testing results  
13 that we get from year to year. The testing results  
14 have been on the increase. Last year, at the end of  
15 the fiscal year, we were at .20, which was the level  
16 that we had been maintaining in ground beef for the  
17 prior couple of years, and by the end of the  
18 calendar year though, we were up at .37, nearly .4  
19 percent by the end of the calendar year.

20           So far this year though, in comparison, for  
21 ground beef where we had .20 at this time last year,  
22 this year we have .40 in terms of our percent

1 positive rate. And we heard some information  
2 yesterday that it may be our testing methodology  
3 that may be contributing to this. The Agency does  
4 not believe that to be the case but it obviously is  
5 an issue for which we need to further assess whether  
6 or not the methodology does have an impact in terms  
7 of the percent positive rate.

8 For beef trim, we started this program in  
9 March of 2007. Our positive rate at this time last  
10 year was .42 in beef manufacturing trim versus today  
11 it's .71 in terms of the calendar year through  
12 October 7th. So we believe that there's an increase  
13 in terms of the indicators that we have for positive  
14 product getting through the slaughter operation,  
15 through the trim on fabrication operation into the  
16 grinding operations.

17 So the purpose of the guideline then was to  
18 provide information about what we think is  
19 appropriate design for sampling and testing  
20 programs. Our primary focus was on beef  
21 manufacturing trim because that's the opportunity at  
22 which industry has put in place, for the most part

1 in the large operations, 100 percent testing of all  
2 production lots associated with manufacturing trim.

3 From our checklist that we conducted last  
4 fall, in which we looked at production practices  
5 within the beef sector, not all operations or  
6 testing beef trim, but the large operations we  
7 believe to be, in fact, testing 100 percent of the  
8 production lots that go out the door.

9 We also wanted to provide information to  
10 assist in the development of the programs to assess  
11 adequacy of process control. Indicators other than  
12 O157:H7 could and should be used to indicate process  
13 control and from the questions that we asked from  
14 our checklist, identified that establishments  
15 generally are not at least documenting that they're  
16 looking at other microorganisms than O157:H7 or  
17 necessarily having production practices in place  
18 that would identify their systems are well  
19 controlled.

20 And then we wanted to provide some guidance  
21 in terms of sampling and testing programs that could  
22 lead to reductions in contaminated product, meaning

1 that testing alone as we've heard before, and that  
2 the Agency firmly believes testing cannot be used to  
3 put safety into the system. It's an indication of  
4 whether or not the system is working, but any  
5 effective system has to have a feedback loop so that  
6 there can be continuous improvement in that  
7 operation.

8           We did identify principles related to  
9 statistical process control for O157:H7, and I'll  
10 walk you through the primary principles that were in  
11 this document. We did identify the contamination  
12 during slaughter dressing is reasonably likely to  
13 occur even under good manufacturing practices. In  
14 the Agency's Federal Register documents in which  
15 we've told industry that we believe they need to  
16 reassess beginning in 1999, 2002, and again in 2005,  
17 and more specifically in 2002, the Agency said that  
18 we could not see how a slaughter operation could  
19 operate without at least one critical control point  
20 to address O157:H7 because we, the Agency, believe  
21 that O157:H7 is reasonably likely to occur in that  
22 operation.

1           The second principle was that contamination  
2 should be minimized to the maximum extent practical,  
3 realizing that we're not working in a sterile system  
4 whereby the carcasses will not become contaminated.  
5 At this time, there are no practical interventions  
6 in place that can eliminate completely O157:H7 other  
7 than on the carcass irradiation, but that is not  
8 used in this country on beef carcasses, and so we  
9 are working in the mode of minimizing to the maximum  
10 extent practical the level of contamination.

11           Thirdly, the decontamination treatment  
12 should remove *E. coli* O157 to the maximum extent  
13 practical and to a non-detectable level. In the  
14 Agency's documents that published in the Federal  
15 Register in 2002 and 2005, we did identify that our  
16 goal would be to ensure that production lots of  
17 product going out the door in each operation that  
18 has, in fact, passed pre-shipment review, should be  
19 at a level in which O157:H7 would be non-detectable.

20           With that then, in order to ensure that,  
21 there needs to be some understanding about the  
22 capability of the slaughter/dressing operation

1 through validation. This is an area for which we  
2 think that the Agency has not focused on the content  
3 and degree of validation that occurs with production  
4 practices. It is an area for which we are  
5 refocusing and again getting at some of the issues  
6 raised earlier, in that there are mechanisms in  
7 place to demonstrate that production systems are, in  
8 fact, known in terms of their capability to address  
9 the level of contamination coming into operations.

10           It is the Agency's belief that  
11 contamination levels likely do change over the  
12 course of the year due to seasonality effects with  
13 0157:H7. Again, we believe that contamination is  
14 greater during certain months of the year than in  
15 others and that the slaughter/dressing and other  
16 production practices should be adjusted to address  
17 this greater level of contamination, and so  
18 operations should know the capability of their  
19 systems and adjust them accordingly and have data to  
20 support that their systems are, in fact, capable.

21           And, in addition, microbiological  
22 indicators of process controls should be

1 established. The Agency has stressed that we do not  
2 see how you can demonstrate your system is producing  
3 a non-detectable level of O157:H7 without testing  
4 for *E. coli* O157:H7, but we also recognize it is not  
5 the organism that you would use to demonstrate that  
6 you have process control. There are other  
7 indicators of process control that any effective  
8 HACCP system should be using in addition to the  
9 monitoring and verification that would occur on a  
10 day in and day out basis. And so the indicators of  
11 process control should be used to demonstrate that  
12 there's continuous improvement for reductions of  
13 contamination in the operation.

14 Another principle was that sampling and  
15 testing for O157:H7 should occur at a frequency  
16 sufficient to find evidence of contamination exiting  
17 the slaughter dressing operation. Our best practice  
18 guidance documents that we've issued, that we know  
19 at least the larger operations are following, is  
20 that every production lot is sampled and tested for  
21 *E. coli* O157:H7 using an N-60 methodology designed  
22 to find contamination.



1           The results of that testing then should  
2 inform the HACCP system. There should be a feedback  
3 loop whereby information from the trim manufacturing  
4 operation should feed back to the slaughter  
5 operation in those circumstances where positives are  
6 found, and investigations should occur to determine  
7 whether or not the system was operating properly.

8           Likewise, when there are contamination  
9 events or other failures during the slaughter  
10 dressing operation, there should be a feedback loop  
11 to the trim manufacturing operation to inform  
12 whether or not the contamination is there when it  
13 might not otherwise be indicated to be there, simply  
14 because of actions that occurred during slaughter  
15 dressing, and so there should be a feedback loop in  
16 both directions.

17           In addition then, the adequacy of the  
18 sampling testing program should inform whether or  
19 not you're able to detect those kind of system  
20 failures that are occurring either sporadically or  
21 systemwide failures whereby more contamination is  
22 getting through the system than what you would

1 normally find.

2           We also identified the principle that the  
3 high prevalence months for O157:H7 are known and  
4 should be addressed. This is an area for which the  
5 Agency clearly is looking for additional  
6 information, research related to this issue as to  
7 whether or not the months in which high  
8 contamination events occurring are changing. We've  
9 traditionally looked at April through the end of  
10 September, October as the high prevalence months,  
11 although in the Agency's testing program, we do find  
12 a fair number of positives towards the end of the  
13 Fall into the end of the year.

14           Of course, we're looking at ground beef and  
15 frozen product, and there are other issues related  
16 to that, but in any case, the high prevalence  
17 seasons have been known in this country for some  
18 time, and we believe that controls should be put in  
19 place to address the higher likelihood that this  
20 pathogen is coming on carcasses to the slaughter  
21 operations and that the events for contamination may  
22 be occurring at a higher rate and contamination may

1 be at a higher level during these periods of time  
2 and that production practices should, in fact, be  
3 adjusted to address this higher expected  
4 contaminating event, and that the data should be  
5 present to show that, in fact, that process is  
6 controlled.

7           The Agency believes that the production  
8 operations should be controlling at the low  
9 prevalence rate in terms of percent positives and in  
10 terms of performance during the slaughter dressing  
11 operation.

12           We believe that the contamination may  
13 overwhelm these slaughter dressing operation such  
14 that more contamination is simply getting through  
15 the system, and in part, this is what we believe is  
16 happening during the high prevalence season months,  
17 and that we find more positives during this period  
18 of time indicating that more product is, in fact,  
19 contaminated perhaps at low levels, but every  
20 opportunity of testing is an opportunity to find the  
21 organism and to remove product from the system and  
22 then to adjust the system.

1           Trim testing and sampling for O157:H7  
2 provides an indication of the adequacy of the prior  
3 control. Programs should be designed to provide  
4 high confidence that contamination is minimized and  
5 at a low level.

6           We identified the principle that sporadic  
7 positive test results are expected. A well  
8 operating program should be one designed to find  
9 positives and to address those positives, and a  
10 system should be articulated such that you know the  
11 difference between your sporadic rate that you  
12 expect at all times during the year and evidence  
13 that there is process control failure. We believe  
14 that a production process cannot operate properly if  
15 you can't identify a distinction between the two.

16           With this, then, we identified that  
17 multiple positive test results involving same source  
18 materials, which generally is what we're dealing  
19 with when we're talking about beef manufacturing  
20 trim, is evidence of a high event day. It could  
21 indicate that there is a systemic failure either  
22 developing or that has developed to adequately

1 control for the presence of 0157:H7 and therefore  
2 the process is out of control.

3 In these circumstances, negative test  
4 results are suspect by the Agency whereby we would  
5 consider them to be false negatives and that  
6 insanitary conditions likely have occurred in that  
7 operation such that not only is the trim and the  
8 negative test on trim affected, but primal cuts and  
9 other products produced in that operation are, in  
10 fact, affected by that determination. This is in  
11 part the determinations that the Agency used in a  
12 recent recall from this past summer in which we  
13 declared that there were insanitary conditions and  
14 primal cuts in addition to manufacturing trim were  
15 affected by that decision.

16 From this, then, our testing results for  
17 trim and how we use them, FSIS did conduct a  
18 nationwide baseline survey in which we looked for  
19 the presence of 0157:H7 in manufacturing trim  
20 available for commerce. The criteria were  
21 specifically established that we would only use the  
22 testing results from trim that had been released by

1 the establishment for the production in raw ground  
2 beef operations. This is not a baseline study to  
3 look for the prevalence of O157 on beef. This was a  
4 designed study to look for the prevalence of O157 on  
5 trim that had been produced in an effectively  
6 operating system as determined by each establishment  
7 and released for the purpose of using in raw ground  
8 beef.

9 Our results identified that the trim  
10 positive rate then was .68 percent of the samples  
11 that we tested were positive. Some of these samples  
12 were pretested by industry. The survey was done  
13 nearly three years ago, between three and two and a  
14 half years ago, and so it was at a time for which  
15 the larger operations were testing 100 percent of  
16 their trim for O157:H7, that many smaller operations  
17 were not, and today many small operations are not  
18 testing the trim as well. But in any case, at that  
19 time, the samples available for raw ground beef  
20 production tested .68 percent positive.

21 So that is the percent positive rate that  
22 we found in this nationwide baseline survey.

1           Some, but not all of these samples were  
2 pretested, and we identified that. The Agency does  
3 not have information to identify how many of the  
4 production lots we sampled were pretested.

5           We also had anecdotal information from  
6 industry that suggested that the average annual  
7 positive rate in pretested trim despite industry is  
8 between 1 and 2 percent, realizing that the rates  
9 are probably different in the low prevalent season  
10 than in the high prevalent season, but the average  
11 was between 1 and 2 percent.

12           So the FSIS then selected 1.5 percent as a  
13 guidance value for purposes of deriving a high event  
14 day criteria for identifying potentially false  
15 negative results. Again, it was important to  
16 identify a percent positive rate in manufacturing  
17 trim likely available for commerce in order to begin  
18 the process of discerning statistically anyway the  
19 difference between sporadic positives and those  
20 which might indicate that there is a systems failure  
21 because there is a high number of positives in like  
22 source product.

1           And, again, our production practices within  
2 the industry, and that has been accepted by the  
3 Agency, is that we have point source contamination  
4 generally when good manufacturing practices are in  
5 place, because there are same source materials used  
6 in the production of manufacturing trim and trim is  
7 segregated into individual units based on space and  
8 time, even though they have generally same source  
9 materials in them.

10           And so it was important to be able to  
11 discern differences as to sporadic positives or  
12 indications that the contamination rate is actually  
13 high.

14           For verification testing, then testing  
15 should be for both O157:H7 as well as for microbial  
16 indicators or process control. Although in the  
17 National Advisory Committee for Micro Criteria for  
18 Foods document on HACCP, that committee did identify  
19 that generally a HACCP system should not require end  
20 product testing if the validated safeguards in place  
21 are, in fact, effective.

22           However, with O157:H7 being an adulterant



1 in raw product and there are no interventions widely  
2 used that would eliminate this pathogen in raw  
3 products, then at this point in time, the Agency's  
4 belief is that microbiological testing of finished  
5 product in this case, manufacturing trim, is, in  
6 fact, a necessary component to ensure that adequate  
7 controls are in place for O157:H7.

8           Testing should occur at all opportunities  
9 where raw beef is handled prior to the sale to the  
10 consumer. Again this gets at the issue of ensuring  
11 that there is a non-detectable level of O157:H7 in  
12 raw beef as it goes through the system.

13           Each testing event provides added  
14 confidence that O157:H7 was present, if it is  
15 present at a low level sufficient to remain non-  
16 detectable.

17           The Agency in this guidance document then  
18 did provide some guidance to small and very small  
19 plants who, for the most part, are purchasers of  
20 beef manufacturing trim for use in their production  
21 practices. We do provide guidance to small plants  
22 in order to give them resources and to help them

1 make some decisions about how they can demonstrate  
2 that their systems individually are operating  
3 properly.

4           It's not enough just simply to rely upon  
5 the grant of inspection for product moving from one  
6 establishment to another. That grant of inspection  
7 is an evidence from the Agency that the system  
8 producing that product was operating in accordance  
9 with the system that that establishment designed.  
10 It is not a guarantee that the product is free of  
11 O157:H7.

12           And so the guidance that we provided to  
13 small plants was based on the premise that the  
14 source materials were tested 100 percent.  
15 Production lots were, in fact, pretested. So this  
16 would give minimum frequencies for testing assumed  
17 that these production lots were pretested, and then  
18 we provided guidance that there should be increased  
19 testing in terms of high prevalent seasons so that  
20 there can be added confidence that if low level  
21 contamination was getting into the system, that it  
22 might be found.

1           We segregated this into the four categories  
2 that were mentioned yesterday in that we have our  
3 inspectors collect information at least identifying  
4 on each sample form the production in that  
5 particular establishment on the day in which the  
6 sample is collected. And so we segregated it into  
7 those establishments producing greater than 250,000  
8 pounds of product a day versus those who produce  
9 more than 50,000 but less than or equal to 250,000 a  
10 day, and then those that produce more than 1,000  
11 pounds but less than or equal to 50,000 pounds per  
12 day, and then those that produce less than or equal  
13 to 1,000 pounds per day. This ranged from greater  
14 testing in the largest volume category to more than  
15 one sample per month, in the next highest category  
16 at least monthly, the third highest category then  
17 being at least once every other month, and then for  
18 those smallest operations who are producing product  
19 for which they're purchasing trim at least once a  
20 quarter.

21           The sampling guideline then as well  
22 identified that the establishments must define the

1 production lot which is, for the most part, a  
2 sampled lot. They're one and the same.

3           If the same source materials are present in  
4 other production lots, establishing microbiological  
5 independence is therefore essential, and so they  
6 must have a program designed such that a sample  
7 collection procedure can find point source  
8 contamination, and again our guidance is that this  
9 should be at least N-60. From our checklist that we  
10 conducted last fall, we did identify that there are  
11 many establishments using something other than N-60.  
12 In any case, we believe that at this point in time,  
13 N-60 is the gold standard that should be applied  
14 across the board on beef manufacturing trim.

15           The production lot size is a critical  
16 consideration. The larger the lot size, the greater  
17 the vulnerability for not finding O157:H7. It's the  
18 more product then is impacted by the decision of  
19 that sample.

20           The Agency's guidance is that it's best to  
21 collect the entire sample from each combo bin for a  
22 composited sample representing the lot. We know

1 that this is not the common industry practice, but  
2 we believe that it does reduce risk if, in fact,  
3 each individual combo bin is treated separately.  
4 And then if box trim is available, such that it's in  
5 60 pound boxes or some other size box and is sent  
6 into commerce in that manner, then there should be  
7 samplings from one or more of those boxes or units  
8 in order to get a composited sample representing the  
9 lot.

10           It's important then in the guidance that we  
11 identified that you need to understand the lab  
12 testing method capability. FSIS analyzes 325 grams  
13 of a composited sample. There is a need to know the  
14 laboratory procedure that is in place within each  
15 operation because each lab can analyze things  
16 differently, and we know that industry for the most  
17 part doesn't specifically look for *E. coli* O157:H7.  
18 It's looking for generally a host of triggers or  
19 target genes or other components that would identify  
20 more than just O157:H7, but for which that screen  
21 is, in fact, including O157:H7, and we do consider  
22 this to be a more conservative approach than looking

1 only for O157:H7 because it is our belief that  
2 samples positive for O157:H7 likely are also  
3 positive for non-O157:H7 Shiga Toxin forming *E.*  
4 *colis* which is an issue for which the Agency  
5 identified that we are pursuing in terms of  
6 developing with ARS laboratory methodologies to, in  
7 fact, look for six of those particular components in  
8 the samples that we collect.

9 We also identified that there was industry  
10 practice that from an efficiency standpoint, some  
11 laboratories do, in fact, enrich samples and then  
12 combine those samples so that they're analyzing  
13 fewer samples for an efficiency measure but have  
14 also developed validating data to demonstrate that  
15 they don't lose any sensitivity or specificity with  
16 regards to their methodology.

17 And so in some cases, samples come in, are  
18 individually enriched and then aliquots are pulled  
19 from those samples. They're combined. I put  
20 composited here. I think pooled is probably a more  
21 appropriate term used by the laboratories, but in  
22 any case, that sample is analyzed. If it's

1 positive, then there may be a determination made to  
2 go back and look at the individual or enriched  
3 samples to find out which particular production was,  
4 in fact, positive and we heard yesterday that there  
5 may be some concerns about that process, but in any  
6 case, we would expect there to be some validation  
7 associated with that process. But it is one way to  
8 ensure some lab efficiency in terms of decreasing  
9 the number of samples analyzed but it also does  
10 present some risk with regards to product that may  
11 be released that actually might be positive but only  
12 tested negative.

13           In this case, going back and looking at the  
14 individual enrichment, it would not be considered  
15 retesting by the Agency, and I do want to stress  
16 that the Agency considers any retesting of positive  
17 product to be inappropriate, and we would not find  
18 that acceptable I think under any circumstance. So  
19 we do draw a distinction between further  
20 characterizing whether or not a sample is negative  
21 or not, but not first looking at a positive sample  
22 and then trying to provide that it actually was

1 negative.

2           We think the proper interpretation of the  
3 sampling and testing results for a well-designed  
4 program is critical for ensuring that false negative  
5 product is not released for use in raw ground beef.

6           Using the data the Agency has available to  
7 it, because the Agency has never received  
8 information from industry as to what the positive  
9 rate is for the trim programs for which they  
10 operate, so this would be the product for which  
11 establishments release into commerce as raw beef  
12 produced product, the Agency is then using the 1.5  
13 percent as a guidance criteria, with that then some  
14 measures using statistical parameters can be  
15 identified to give us a 95 percent confidence level  
16 as to whether or not a production process is  
17 producing product at greater than that 1.5 percent  
18 positive rate that I identified as a guidance level.

19           In this particular case, the guidance  
20 document has a table in it that identified a variety  
21 of different positive numbers with regards to  
22 production lot sizes and to make a determination as



1 to whether or not there are more positives than what  
2 would be expected if the contamination rate was less  
3 than 1.5 percent in all those production lots.

4           With that then, if there were 55 individual  
5 production lots, these would be microbiologically  
6 independent production lots, through N-60 testing,  
7 for a given period of time, and again this could be  
8 in a day, this could be over the course of time,  
9 particularly for small plants, in this case 3  
10 positives could indicate a systematic failure for  
11 control of O157:H7 in the source materials. Again,  
12 this is using the assumptions that the Agency  
13 provided on the data that we have since we have no  
14 other data to use as a guide. We did identify in  
15 the guidance document that each individual  
16 establishment should identify its criteria for  
17 discerning when product is, in fact, more than just  
18 evidence as having more than sporadic positives, in  
19 this case, the determination being made between  
20 sporadic and systemic failure, realizing that the  
21 industry uses a screening methodology that's looking  
22 more broadly, more conservatively from our

1 perspective, looking at more than just O157:H7, the  
2 positive rate would be expected to be higher and  
3 that that might be criteria that an individual  
4 establishment might use for its distinction between  
5 sporadic positives and those that evidence the  
6 process might be out of control.

7           We did identify that a properly designed  
8 raw beef HACCP system then would have feedback  
9 mechanisms to reduce the likelihood of systemic  
10 failure to control for O157:H7. Again, each  
11 positive event should, in fact, lead to an  
12 investigation to understand whether or not the  
13 production practices at slaughter/dressing were, in  
14 fact, properly applied as well as whether or not the  
15 trim testing results provide some evidence that the  
16 system might not be operating as expected. Again,  
17 this might be due to a combination of more  
18 contamination coming into the system or a particular  
19 failure of the system to prevent the contamination  
20 from getting out of the system.

21           Again, the document was written for the  
22 purposeful intent of looking at slaughter operations

1 that also fabricate the trim, so that there could be  
2 a very direct feedback loop between the two  
3 operations. However, this guidance is intended to  
4 also be effective for operations that purchase trim  
5 and that the individuals who purchase that trim and  
6 have a testing program in place on the trim or the  
7 ground beef would be providing feedback to the  
8 supplier so that there could be evidence built to  
9 demonstrate that the systems might, in fact, not be  
10 properly controlling for 0157:H7.

11 In terms of next steps, these are the  
12 intentions of the Policy Office with regards to  
13 where we would like to go with the guidance  
14 document. We're here today to get verbal comments,  
15 but we are, as well, accepting written comments  
16 through November 17th. The intention is to get  
17 information that would inform this document so it  
18 could be good guidance for industry as well as for  
19 FSIS personnel so that when they look at a food  
20 safety system, they can, in fact, make some  
21 distinctions as to whether or not the program is  
22 actually designed to control for 0157:H7. This

1 would be at all points in the production process,  
2 and this would be looking to see if there is a  
3 feedback loop between slaughter, between trim  
4 manufacturing, between primal cut develop and bench  
5 trim, between that and mechanically tenderized steak  
6 operations and then with grinding operations.

7           We believe that the document then can serve  
8 as a useful tool. We're looking for your input as  
9 to how to enhance it and improve it so that it is,  
10 in fact, appropriately articulating what a good  
11 operating system should be reflecting, and we also  
12 think that it's necessary through the public comment  
13 to help ensure that we have an understanding of the  
14 controls for O157:H7 throughout the raw beef  
15 operations as well as what the Agency does for its  
16 controls, and that it's critical to have consistency  
17 and uniformity where practical in terms of the  
18 design of the sampling and trim programs.

19           It is our intention to update the guidance  
20 with the input that we do get and then to issue it  
21 as final guidance after we've fully assessed the  
22 comments and reviewed it.

1           If we were to use this document in terms of  
2 a compliance guideline, we obviously would post it  
3 to the webpage. We're asking for comment on it now.  
4 The Agency would continuously update it as new  
5 information is presented that we need to consider.

6           We also think that it would serve as a  
7 useful tool in terms of training, particularly for  
8 our own employees but through some of the activities  
9 that Karlease identified through outreach for  
10 industry as well.

11           And so with that, I think, Mr. Almanza,  
12 I'll just ask if there are any questions or comments  
13 from the audience, and we'll start there.

14           Yes, we have a question out here.

15           MS. HATCH: Yes, my name is Michelle Hatch.  
16 I'm with Greater Omaha, and I'm also a  
17 microbiologist. I have a question on more of the  
18 data. Do you plan on taking the data at all and  
19 breaking it down into I guess different components  
20 in order to not have it so broad for future  
21 references in order to get past some of the old data  
22 that's being utilized from 2003, 2004, so that next

1 year in this type of meeting or things like that, in  
2 moving forward, we can actually have a certain set  
3 year of when we'll actually have some good  
4 comparisons is what I'm referring to here.

5 DR. ENGELJOHN: Okay. Well, I can say with  
6 regards to the baseline data that we had, this was  
7 from data that's now more than a couple of years  
8 old, and so the Agency has identified, it is our  
9 intention to do, as continuously as we can,  
10 baselines, and so one of the issues would be for the  
11 Agency to consider what are we doing with regards to  
12 baselines. Is there a way that we continuously have  
13 a statistical baseline such that we're not doing  
14 them once every 5 years or every 10 years because  
15 again recognizing this baseline data is actually  
16 from a couple of years ago.

17 So there is the intention to do that, but  
18 presently we have that number. It's the only number  
19 that we actually have for a baseline on beef  
20 manufacturing trim.

21 The other data that we have then relates to  
22 our annual percent positive rate and so we look at

1 that on an annual basis. The Agency has tied the  
2 percent positive rate that we find in our regulatory  
3 testing program to the Healthy People 2010 Goals so  
4 that we know, as was mentioned at the beginning of  
5 the meeting yesterday, what the contribution of  
6 ground beef is to the public health burden. We  
7 haven't yet built in the measure for the  
8 contribution of trim to that. So there will be the  
9 intention of looking at all of the components that  
10 are used for raw ground beef, not just beef  
11 manufacturing trim. One of the National Advisory  
12 Committee recommendations to us was that we should  
13 be looking at head meat, cheek meat, low temperature  
14 rendered products which we presently don't have  
15 built into a baseline study, and we really don't  
16 know what the contribution is on those percent  
17 positive rates. So there are a number of things I  
18 think the Agency is looking at to see what is the  
19 best reflection of the percent positive rate in  
20 products available for production, and the Agency  
21 previously hadn't considered a baseline study to  
22 actually identify what is the prevalence of O157 on

1 carcasses before the interventions which I think  
2 would also be an important thing for us to look at.

3           So there are a number of things that we're  
4 considering.

5           Any other questions? Yes.

6           MS. ROSENBAUM: Good morning. I'm Donna  
7 Rosenbaum from STOP, Safe Tables Our Priority, and I  
8 also have concerns about the baseline studies, and I  
9 appreciate the fact that we're here studying  
10 sampling and studying what's been done so far. I  
11 think the problem is that we're two to three years  
12 behind the ball here with what's already rolling  
13 down the track and being done. And it would have  
14 been nice to have a meeting like this in 2004, 2005.  
15 We can't do that. We can't go back, but in looking  
16 at the data that you've got and what you're basing  
17 things on, I have to agree that I'm very concerned  
18 that the variable of the prevalence rate is so  
19 important in informing the whole system, that  
20 without that data, we don't see how you can build an  
21 accurate system around it without knowing that at  
22 the very beginning.



1           So I think while you want to take what  
2 you've got and run with it and do the best you can  
3 at the time, I think you've got to do more than  
4 think about getting baseline data. You have to have  
5 good baseline data now, going forward, continue it.  
6 This organism evolves and changes over time as do  
7 industry practices. You're going to have to  
8 continuously be monitoring for this organism in  
9 trim, in ground beef, to have real good information  
10 that's informing your systems.

11           And without that, we're a little unsure of  
12 how you can base judgments and inform the system at  
13 this point. You know, taking a 1.5 number at this  
14 point is a little bit like a rabbit out of the hat.  
15 We don't know what it is and that variable is so  
16 important for the system. So you really have to  
17 move very quickly to get as much information as you  
18 can to inform the system to put something in place  
19 that's going to be effective over time.

20           DR. ENGELJOHN: Thank you. And I think  
21 your points are well taken. We recognize that, and  
22 we certainly are looking at ways that we can get at

1 that in a shorter timeframe than what normally  
2 occurs for us, which is to design a study and  
3 operate it for a year and then have that data.

4 So continuous baselines, ways to look at  
5 the industries positive rate to inform that as well  
6 would be one thing for us to consider that we have  
7 never done before. So, thank you. We'll certainly  
8 look into that.

9 Yes.

10 MS. KOWALCYK: Barb Kowalcyk, CFI. First  
11 of all, I want to say I was happy with a lot of the  
12 things that I was seeing in the document. I think  
13 it's going in the right direction.

14 I did have a couple of concerns. One is I  
15 think there needs to be a better definition of what  
16 microbiological independence is. It seemed awfully  
17 vague to me, and I'd like to see much clearer and  
18 more concrete definitions because this is going to  
19 be critical in determining what product gets  
20 diverted and what product doesn't, and I just think  
21 that the document is a little vague, and I'd like to  
22 hear more thoughts on that.

1           The other thing is if you go back to your  
2 slide where you have the testing for process control  
3 where you had that little chart, and it said you  
4 have something like, for plants that produce more  
5 than 250,000 pounds a day, you're going to test  
6 greater than 1 per month, and I believe if I recall  
7 correctly from the compliance document, that  
8 there's, I think it's Table 1, FSIS had said that in  
9 order to determine if a process was out of control,  
10 you'd have to see two or more positives out of 24  
11 samples.

12           Now, I understand that based on what you  
13 said, Dan, this is assuming that the product had  
14 already gone through process control sampling, but  
15 earlier, it's not in the document to me about that  
16 because based on this table, my initial reaction was  
17 it could take somebody three years to figure out  
18 that their process is out of control and as a  
19 consumer, that's unacceptable. You know, it needs  
20 to be very clear that this will not provide adequate  
21 feedback on process control in a timely manner, yet  
22 throughout your presentation, throughout the

1 document that's what you said the point of this  
2 testing is, is to provide an assessment of process  
3 control and I think most people would agree that,  
4 you know, if you're doing testing once, four times a  
5 year, it would take you six years to figure out that  
6 your process is out of control.

7 DR. ENGELJOHN: Thank you. I appreciate  
8 that, and I will say being one of the principal  
9 authors of the document, that the document is a  
10 compilation of multiple things, and there needs to  
11 be some clear distinctions very distinctly between a  
12 slaughter fabrication operation that has control at  
13 that point and then different guidance perhaps  
14 developed for those who receive that product and how  
15 they would use it as well as for grinders.

16 So it has a mishmash of all that's  
17 contained within it, and I think your point's well  
18 taken. We can definitely work on that issue. And  
19 we'd welcome any written comments on that on how to  
20 improve it as well.

21 MS. JOHNSON: Do you want to check the  
22 phone line, Dr. Engeljohn? Check the phone line as

1 well.

2 DR. ENGELJOHN: Oh, yes. Before I take  
3 this next one in the room, Operator, are there any  
4 questions from the callers?

5 OPERATOR: At this time, I have no  
6 questions in queue. If you'd like to ask a  
7 question, please press star and 1.

8 DR. ENGELJOHN: Are there individuals on  
9 the line?

10 OPERATOR: Yes, we have about 16, 18  
11 participants.

12 DR. ENGELJOHN: Wonderful. Okay. Thank  
13 you. Thank you. Yes, Felicia.

14 MS. NESTOR: Felicia Nestor, Food and Water  
15 Watch. Dan, I've got a question about how involved  
16 the Agency is going to be in these programs. You  
17 know, reserving judgment about whether or not we can  
18 support the process control aspect that you've  
19 proposed, I mean it's my understanding that  
20 inspectors have not been very involved at all in  
21 making sure that plants are following up on a  
22 positive and, you know, once you have multiple

1 positives, that gets to be another level of analysis  
2 and then you also have the feedback loop between the  
3 slaughter floor and the trim floor which, you know,  
4 that product is going to be on the trim floor. I  
5 don't know what it is, maybe two days later or three  
6 days later, and so, you know, I guess my question is  
7 has OFO agreed to allow the inspectors to  
8 participate in this and have you started drafting  
9 any instructions that inspectors will be, you know,  
10 following when this is in place?

11 DR. ENGELJOHN: Thank you. This is  
12 Engeljohn. What I would say is that within the  
13 Agency presently, we recognize that the systems we  
14 put in place have really not focused upon this  
15 systems approach other than for the most part our  
16 EIAOs looking at our food safety assessments, to  
17 look at the overall food safety system, and so the  
18 individual employees in the plant every day have  
19 been tasked with looking at plant data but there's a  
20 great deal more that needs to be done than just  
21 looking at the data. And so the systems we have in  
22 place presently aren't designed actually to address

1 it as comprehensively as what they could be but I  
2 can tell you that we are working on a couple of  
3 policy documents that are going through the  
4 clearance process which gives the internal program  
5 areas the opportunity to comment but, but for the  
6 most part, we are focusing on slaughter/dressing and  
7 those activities there, as well as in those  
8 operations that have trim fabrication as part of  
9 that slaughter operation, how then the two  
10 operations need to be looked at as a system which  
11 isn't specifically what we would do today in a very  
12 defined way. So that would be in the form of a  
13 policy document that is under development.

14 If it does issue, and I think there's merit  
15 to it, but we certainly will work that through that  
16 process, there will need to be a very strong  
17 training component with that as well, and if that  
18 policy moves forward, clearly it would have the buy  
19 in of all the program areas within the Agency.

20 So from our perspective, we recognize we  
21 need to focus on a more systemic approach in plant  
22 every day as opposed to relying upon the food safety

1 assessment specifically to identify problems, and so  
2 that is an area that we are, in fact, focused.

3 Yes.

4 MS. HATCH: Yes, Michelle Hatch with  
5 Greater Omaha. Yes, I don't kind of want to take  
6 away from that piece of it, and I just want to say  
7 that as safety and being a U.S., you know, resident  
8 and everything, we have the safest food basically in  
9 the United States and we got that from everybody in  
10 this room coming together, and first of all, I just  
11 want to make sure that nobody loses sight of that.  
12 So that means that somewhere along the line, FSIS,  
13 the industry, the consumer groups, everybody has  
14 come together to make that happen, and we just need  
15 to make sure that everybody knows that it has been a  
16 collaborative effort in making that happen because,  
17 not one industry or group, and that has solely been  
18 able to do that and make this a process, and so it  
19 has been a collaborative effort among everybody.

20 And I think that, Dr. Engeljohn, that, you  
21 know, the FSIS in the districts, we have a really  
22 great district actually in the area that we are,



1 that really uphold a lot of what's been up here on  
2 these bulletins and the PowerPoints, and I think  
3 it's more about the unity of going across the  
4 districts, and I think probably in Karlease Kelly's  
5 outreach programs, that it's a matter of gathering  
6 information as to which districts are actually doing  
7 better in conveying the messages from Washington and  
8 utilizing them in your outreach programs to the  
9 other districts, would be just a recommendation.

10 DR. ENGELJOHN: Thank you. I do want to  
11 also just touch on that. I agree that there does  
12 need to be a good working relationship at the plant  
13 level with the inspection force, and the  
14 inconsistencies across district lines is always an  
15 issue that I think we tackle on a day-to-day basis.

16 I will say though that we do know that  
17 there are differences in the levels of control  
18 amongst the establishments, and coming up with at  
19 least some minimum level of what we would expect for  
20 everyone, not on a regulatory format at this point  
21 in time, but at least getting all operations up to  
22 having programs in place that at least are

1 demonstrated to be effective is something that we  
2 will continue to strive for, and I think it does  
3 point out there are differences amongst  
4 establishments. There are poor performing  
5 establishments for which the Agency is focused and  
6 it's not focused just to put our resources there and  
7 continue to get them there but it's to ensure that  
8 those establishments actually develop their programs  
9 into effective food safety systems and that's a  
10 focus I think that we need across the districts we  
11 have a need to put a little more effort. So thank  
12 you.

13 Yes, in the back.

14 MR. DANIELSON: Thank you. Dean Danielson,  
15 Tyson. Dan, and I hope everybody, you know,  
16 everybody did hear you, training, things as we  
17 learn, we implement things and develop new things to  
18 address the new learnings and training is a very  
19 difficult task across multiple companies, multiple  
20 plants and FSIS. I mean this is a very complex  
21 matter that we're talking about, not only just how  
22 to go out and cut a piece of meat off, but then as

1 these reviewers or EIOs go in or company people, as  
2 we go review raw material suppliers and our  
3 auditors, it's very, very complex, the lab methods  
4 that are in place. How do you look at validation  
5 data and assess that within the process that's  
6 there. Is it legitimate? Is it, you know, is it --  
7 I use different slang terms, but is it worthless or  
8 is it not very good. So it's very challenging to  
9 get people up to speed and to get them.

10 I've got an anecdotal story here for you,  
11 Dan, and just last week, this was in FSA, we were  
12 having in one of our plants, the EIAO, this is the  
13 first time in history, in my history that this ever  
14 happened, the EIAO went to the laboratory to review  
15 laboratory procedures. This never happened before.  
16 That's an outcome of new learnings and trainings,  
17 and then interestingly enough, the EIAO observed  
18 that in our procedure, we had a modification in the  
19 enrichment process than what the manufacturer had in  
20 their prescription. And he saw that. This is  
21 great. I mean a great observation that was made, an  
22 astute observation with my auditors doing raw

1 material suppliers, I would expect them to see the  
2 same thing, and so then he drove us through the  
3 process of showing us -- show us your validation to  
4 support this alternative enrichment process and we  
5 did have that, and it was an improvement over, from  
6 our standpoint, for validation.

7           But I make that as an observation. It's  
8 the first time this ever happened. I think it's  
9 very good when you guys go into the plant, and for  
10 everybody else to listen to this, it's a long  
11 complex process and it takes a lot of training and  
12 education and intuitive people to go in and look at  
13 these things that are going on and the more  
14 exposures that they have to them. It was heartening  
15 to me to see that type of an in depth analysis take  
16 place rather than, you know, don't take this too  
17 hard but the NRs we get, a piece of paper that's not  
18 signed or a date that might be out, you know, those  
19 types of things that come out of the FSAs that are  
20 more, you know, mundane than a true interpretative  
21 observation of a process validation difference,  
22 that's good stuff. We all need to be better at

1 that. So I'm heartened by that. My people got all  
2 excited when this happened. I thought it was great.  
3 I thought it was great. Thank you.

4 DR. ENGELJOHN: Thank you. I appreciate  
5 that. Anytime we get that anecdotal information,  
6 it's helpful.

7 I will say at least from a commitment from  
8 the Policy Office and the Agency, we are trying to  
9 put out policies that have delayed effective dates  
10 so that there is, in fact, a training component  
11 built into them so that before they're implemented,  
12 there actually is an understanding of the intent and  
13 that we're actually on the same page both our own  
14 employees and the industry as to what we're trying  
15 to do. How we teach somebody to think is a  
16 different issue. I think that we can learn a great  
17 deal from you in terms of the audits that you do,  
18 the types of things you look for to help inform us.  
19 It is an area where I think we need to focus more,  
20 and I'm glad our employees are stepping up to the  
21 plate. So thank you for providing that. Yes.

22 MS. KOWALCYK: Barb Kowalcyk, CFI. I just

1 wanted to play off a comment that he made, and this  
2 is a very complex issue, and I really think that, I  
3 just want to reiterate the point that I made  
4 yesterday is that FSIS really needs to provide  
5 plants with the technical assistance so that they  
6 can develop sampling plans.

7 I'd like to take it even one step further  
8 because I don't think -- you're going to have to  
9 have some sort of oversight on the development of  
10 the sampling plans and the implementation of the  
11 sampling plans because, as the gentleman just  
12 pointed out, garbage in gets you garbage out, okay.  
13 So you need to have a good robust sampling plan  
14 that's implemented correctly so then you can  
15 generalize and interpret your results. And I don't  
16 think that the inspectors have the capabilities or  
17 the time actually to do those activities. So one  
18 thing that we have advocated for is that sampling  
19 plans for the plants should be certified or approved  
20 through some mechanism either by FSIS or by an  
21 independent third party. And that will make sure  
22 that you're really achieving the goals that you want

1 your microbiological testing programs to achieve.  
2 So that's the one comment.

3           The other comment I'd like to make briefly  
4 since I know there's others waiting is I think  
5 really there needs to be more discussion and focus  
6 on the fact that in recognizing that you can't have  
7 a one-size fits all sampling plan, you really need  
8 to talk more about the power of your testing  
9 programs, and make sure that they're again -- it's a  
10 way to evaluate whether or not they're meeting the  
11 objectives that you've set forth.

12           DR. ENGELJOHN: Okay. Thank you. Yes.

13           MS. ROSENBAUM: Donna Rosenbaum with STOP  
14 again, and I'd like to take a comment a little  
15 further again on the testing program and on the  
16 prevalence rate, and reference that in terms of the  
17 overall goals of this program. So I have a comment  
18 and a question.

19           I understand and we support the notion of  
20 differentiating between and having to have a system  
21 differentiating between total system overload with  
22 contamination rates indicating that something has

1 really gone wrong versus there being a low level  
2 sporadic rate that will be background and that we'll  
3 never be able to get this to zero.

4           However, there's a difference between  
5 saying that and then taking the position that that  
6 level that you've set it at, that you know that  
7 there's sporadic rate of is okay, and this is a  
8 lethal pathogen. This is just about the second now  
9 most important toxin to man, and we need to have a  
10 system. I would like to know whether it is a goal  
11 of USDA in setting forth this plan to drive that  
12 number down over time, and if so, we'd like to see  
13 that much more thoroughly implemented throughout the  
14 guidance document.

15           DR. ENGELJOHN: Okay.

16           MS. ROSENBAUM: And we saw some comments  
17 yesterday that indicated that some people in the  
18 industry are looking at it that way, but we'd like  
19 to see that reflected in the USDA material so that  
20 we're not, you know, 10 years ago after HACCP  
21 started with standards that are not being driven  
22 down, that have kind of just set there and set in



1 place. Especially with this pathogen, if you're  
2 looking at this pathogen, it's going to be necessary  
3 to do things and acknowledge that it might be very,  
4 very small and incremental over time, but we do need  
5 to have something in place that drives it down.

6 DR. ENGELJOHN: Great. I appreciate that.  
7 I will say the Agency does have its strategic plan  
8 posted. It is available to look at, and it is  
9 designed actually -- it doesn't have a specific  
10 performance measure in it for beef trim. It's  
11 specific at this time for ground beef, but the  
12 Agency has a number of other performance measures  
13 that we're working towards, and they're built with  
14 the intention of having continuous improvement.  
15 They are not set at a level and they stay there.  
16 They're actually built so that we're constantly  
17 trying to drive down the rate that we have.

18 So it is one way to articulate it, but  
19 clearly we haven't articulated that in a manner that  
20 you can see that. But I will say the way that  
21 presently our risk management programs are designed,  
22 they are designed to identify what we believe to be

1 the current practice and then to set a level that's  
2 going to drive that down further until the point at  
3 which we know that there needs to be some  
4 substantive intervention in place perhaps to take it  
5 to that next level. We don't think we're there with  
6 0157, and so there is the design to continuously  
7 lower that. We'll better articulate that.

8 I think you have a follow up.

9 MS. ROSENBAUM: Would you consider setting  
10 a time. I don't know what that time would be, but  
11 something that everybody would agree upon, whereby a  
12 year after you -- the anniversary date of every year  
13 after you release the compliance document and it's  
14 complete or you're setting some type of standard, to  
15 go back and revisit it so that it's not just  
16 arbitrary out there, well, when we get to it, we'll  
17 do it. I think that should be set forth in the plan  
18 from the very beginning.

19 DR. ENGELJOHN: Okay. I would agree, and I  
20 think it's responsible that we have -- as I said, we  
21 would continuously update them, but we will put  
22 forward an action plan that does, in fact, put some

1 measures in there. It's also important for the  
2 Agency to know that the guidance we put in place is  
3 effective. And we do need input on that as to  
4 whether or not what we've constructed will be  
5 effective, and then as Karlease mentioned with our  
6 training, it's not good enough just to deliver it.  
7 You actually have to have a measure of success. Is  
8 it working?

9           So I agree. An effective program would  
10 design an action plan to get at that, and we'll do a  
11 better job of articulating it.

12           Yes.

13           MS. BUCK: This is Pat Buck from the Center  
14 for Foodborne Illness, Research and Prevention. And  
15 one thing that I think is kind of important as  
16 you're putting this plan together is something that  
17 the gentleman brought up just a little bit ago, and  
18 that is the need to have the types of training  
19 that's actually going to be hands on. Too many  
20 people have to learn -- I mean I'm a teacher. Too  
21 many people only learn a complicated and detailed  
22 operation like what you're asking them to do by

1 hands on training, and that one on one training  
2 would then, of course, I think drive your inspection  
3 force as well as the people working in the industry  
4 to realize that this is really crucially important  
5 that we do this correctly. So I would encourage  
6 when you're putting your plans together, the other  
7 thing I would encourage you to do, is make sure that  
8 the plans are then being implemented because I have  
9 heard from too many different sources that these  
10 HACCP plans get written and then as soon as the  
11 inspector walks out the door or they know FSIS is  
12 not coming back, that the plan goes into a drawer  
13 and is not followed correctly.

14 Now I do not think that happens with the  
15 industries that are committed to food safety, but I  
16 do think that that does happen, and we need to weed  
17 out people that abandon good food safety protocols.  
18 Thank you.

19 DR. ENGELJOHN: Thank you. Our session  
20 goes until noon, so I'm going to keep you here until  
21 you stop asking questions. It's not an  
22 encouragement to stop asking questions, but I do

1 want your input. We do want to improve the  
2 documents we put together.

3 If I could, Operator, are there any  
4 questions on the phone?

5 OPERATOR: I have no questions in queue at  
6 this time.

7 DR. ENGELJOHN: Okay. Felicia.

8 MS. NESTOR: Felicia Nestor, Food and Water  
9 Watch. Someone's comment reminded me about -- well,  
10 a number of comments have reminded me about the  
11 issue of consistency and, you know, I really think  
12 that the Agency needs to put in place a constant  
13 practice of evaluating the extent to which the  
14 policies are being enforced in a consistent manner.  
15 I mean in the last several months, I've heard about  
16 plants that had FSAs, you know, different plants of  
17 the same company, that used the same plan in  
18 different districts and the plan is acceptable in  
19 one district and not in another. And that's really  
20 ridiculous.

21 Anytime I hear anything from an inspector,  
22 you know, I reach out to inspectors all around the

1 country, and too often I hear that a policy in one  
2 area of the country is not being followed in another  
3 area of the country. We were talking yesterday  
4 about the definition of fecal. Supposedly that was,  
5 you know, in a written document as early as, you  
6 know, prior to HACCP and I was hearing about  
7 changing from inspectors years into HACCP.

8 Dan, you and I had a discussion a while ago  
9 about the Tech Center and the instruction that was  
10 being given to inspectors when they go for training,  
11 you know, when they would ask, what do I do if I go  
12 back to my plant, and my supervisor tells me to do  
13 something other than what I've learned in my  
14 training, and what they were told is follow your  
15 supervisor. And we came up with some kind of  
16 process where anytime there was a difference between  
17 a supervisor and an inspector, that conflict would  
18 get elevated and a determination would be made.

19 I just heard recently, and I'll probably be  
20 coming to you with the details privately, about a  
21 plant, again, the inspector has Tech Center  
22 instructions, and the supervisor said we're not

1 doing it this way, you better do it this way. And  
2 apparently, you know, he got OFO signoff on that.

3 So that kind of inconsistency and, you  
4 know, regulation by location just really from a  
5 consumer standpoint is really just not good enough.

6 DR. ENGELJOHN: Thank you. Barbara.

7 MS. KOWALCYK: Barb Kowalcyk from CFI  
8 again. Two things that I think would improve the  
9 sampling and improve the document that I'd like to  
10 see added is, one, you know, one of the things your  
11 sampling plan ought to do is minimize bias and this  
12 is either where you're talking about industry or  
13 FSIS sampling. People inherently will want to do  
14 better if they know they're going to be tested. So  
15 if there is some way to kind of blind the plant  
16 workers to the fact that a test is going to be  
17 occur, it would be very beneficial to do that, and I  
18 know, I think I've brought this up previously  
19 privately with people with FSIS and I know it's  
20 difficult, but I think there are ways that you could  
21 get around that, so the plant doesn't know when FSIS  
22 is going to be taking a sample. Even when the plant

1 itself is doing testing, I would think that they  
2 would want to in some way blind their workers to the  
3 fact that a test is being taken ahead of time  
4 because you really want to get as representative a  
5 sample as possible.

6           Along that same line, I think that there  
7 needs to be more discussed about stratified  
8 sampling, the whole idea, and you do touch upon this  
9 in the document which I think is good, but the whole  
10 idea that if you just take your N-60 or whatever N  
11 you choose, right off the top of the combo bins,  
12 it's really not being representative, and I think  
13 that both FSIS and industry to think about ways that  
14 you could actually stratify those combo binds to  
15 effectively get a better representation of what the  
16 lot is really like, and I think there probably are  
17 ways that you could do that. You just need to -- I  
18 think it'll take sitting down and really working it  
19 out and looking at the whole process to determine  
20 how you could achieve that.

21           DR. ENGELJOHN: Okay. Thank you. I will  
22 say that to the extent that we need to make clearer



1 sometimes why we make the policy decisions that we  
2 do, O157:H7 being an adulterant does create some  
3 circumstances in which we've pulled samples, and we  
4 don't pull samples in a manner such that there's a  
5 likelihood that products have been released into  
6 commerce. So we have some restrictions, but we  
7 certainly can look into other things to get at the  
8 issue of being less announced or less -- a process  
9 by which we can look at that, and I don't know what  
10 that is, but we certainly can look at that.

11 On the stratified sampling, I would say the  
12 Agency, again from a policy perspective in terms of  
13 where we're going and Dr. Esteban mentioned  
14 yesterday, we're looking at some other things in  
15 terms of what we could do to do our job different  
16 and perhaps better. I think we recognize that  
17 pulling those excision samples is a time consuming  
18 process which if there were tools available to do it  
19 differently so that we can get at perhaps more of a  
20 representation from within the combo bin, using the  
21 tool that would get external surface tissue only,  
22 and there are tools available that industry's

1 actually using in some of their own establishments,  
2 might not be commercially available yet, but we're  
3 looking into what can we be doing to sample it  
4 different.

5           So new technologies on that is something  
6 we're always looking at to improve our  
7 opportunities. And I would say that we look at  
8 differences in our verification testing program when  
9 we're just doing our normal verification check  
10 versus when we have reason to go in and do a more  
11 thorough evaluation. It does present the  
12 opportunity to collect samples differently, perhaps  
13 collect more samples in a particular production lot  
14 in order to get better information about that  
15 process, and there is less notice given on those.  
16 So there are some opportunities to look at how we  
17 can sample differently.

18           So thank you for the input, and if you are  
19 going to put that in your comments and have some  
20 suggestions that, too, would be helpful.

21           Jill.

22           DR. HOLLINGSWORTH: Dan, if you could just

1 help me understand a little bit on this small and  
2 very small plant frequency chart that you have, am I  
3 correct in assuming that that is the frequency for  
4 small plants that receive trim and boneless beef  
5 that they intend to grind and their frequency of  
6 every one, two or three months is based on the fact  
7 that the incoming product, the source material they  
8 receive, has already been tested. So this is  
9 actually a second test.

10 DR. ENGELJOHN: Yes.

11 DR. HOLLINGSWORTH: I wanted to check on  
12 that. And secondly --

13 DR. ENGELJOHN: I'll just answer that  
14 first.

15 DR. HOLLINGSWORTH: Okay.

16 DR. ENGELJOHN: Yes, the document actually  
17 explicitly does say there is a presumption that  
18 there was 100 percent testing of all the source  
19 materials elsewhere, being the first thing. And  
20 that as the Agency recommended, we think that the  
21 receiver should test the product at that level and  
22 have a program in place on the finished product

1 perhaps, if they're grinding it as well. But we  
2 realize there are practical considerations  
3 particularly for small and very small plants in  
4 terms of what they can afford to do and the  
5 information they have.

6 I also just want to point out that because  
7 it is the design of many programs where 0157 testing  
8 is the only check that's in place in terms of the  
9 process, and we believe there should be other  
10 process controls in place to give real time  
11 information about the production process. So the  
12 0157:H7 testing isn't the only thing that's  
13 occurring. It's occurring for a specific purpose of  
14 looking for 0157, not looking at their process  
15 specifically. Okay.

16 DR. HOLLINGSWORTH: But so that is a second  
17 test that's done on pretested product?

18 DR. ENGELJOHN: Yes.

19 DR. HOLLINGSWORTH: Yes. Okay.

20 DR. ENGELJOHN: Every opportunity to test  
21 we think should be taken. Okay. At retail as well,  
22 okay.

1 DR. HOLLINGSWORTH: Well, we'll talk about  
2 that. And then I guess since this only applies to  
3 those plants receiving this pretested product, this  
4 would not be the chart that would apply to a small  
5 or very small slaughter operation that's also  
6 generating trim itself.

7 DR. ENGELJOHN: We think that that  
8 operation should have a program in place to address  
9 their trim as well, and our recommendation is 100  
10 percent of the trim should be addressed, whether it  
11 be from their own production or bench trim that  
12 they're pulling in from primal cuts in some fashion.  
13 If it hasn't been pretested, any systems approach,  
14 then they need to have in place a supplemental  
15 program.

16 DR. HOLLINGSWORTH: Okay. Thank you.

17 DR. ENGELJOHN: I'll let you think for a  
18 moment but I will say that Mr. Almanza I think is of  
19 a like mind that in order to beat the lunchtime  
20 crowd, we might let you go to lunch and then come  
21 back and then finish the afternoon earlier. So it's  
22 11:00 now. I suggest that we, unless you have more

1 questions, and I'd love to have your input. You can  
2 talk to me as well off-line, but I think we'll  
3 break. I think we gave you an hour for lunch, and  
4 so if you could be back here at noon, then we'll  
5 start the afternoon session. Okay. Thank you.

6 (Whereupon, at 11:00 a.m., a luncheon  
7 recess was taken.)

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1 on international labeling issues including  
2 import/export labeling and country of origin issues.  
3 Rosalyn.

4 MS. MURPHY-JENKINS: Thank you,  
5 Mr. Almanza. I wish I was 34.

6 Good afternoon, everyone. And I will be  
7 presenting today on the Draft Labeling Policy  
8 Guidance on N-60 Testing Claims for Boneless Beef  
9 Manufacturing Trimmings for *E. coli* O157:H7.

10 As we all know, labels for meat and poultry  
11 products are to convey truthful and not misleading  
12 information. As Dan mentioned yesterday, we posted  
13 web guidance, draft web guidance. It was posted  
14 yesterday afternoon for the labeling of N-60 testing  
15 claims and, of course, as a result of it being a  
16 draft, we are welcoming comments. The guidance is  
17 in draft form. So it will be revised, after the  
18 comment period, and I'll mention that a little bit  
19 later, after the comment period, we'll put it in  
20 final form so that those establishments wishing to  
21 put this voluntary claim on labeling, will have some  
22 guidance in how to do that.



1           We recognize that this is a food safety  
2 issue rather than traditional labeling issues.  
3 Labeling claims do come into our office for review  
4 and evaluation but this type of claim would be  
5 reviewed in a different manner, and I'll give a  
6 little bit more information on that.

7           How did this all come about? The Labeling  
8 and Program Delivery Division received a few  
9 requests for label claims bearing N-60 testing  
10 claims. We had not seen any of these types of  
11 claims before, although there was documentation  
12 presented to support the claim submitted by the  
13 establishment. The Agency recognized that this  
14 draft guidance or some kind of guidance needed to be  
15 provided to the industry to provide a framework for  
16 how these labels can be applied to products and it  
17 be truthful.

18           An establishment may submit such claims as  
19 long as they can demonstrate that these claims are  
20 truthful and not misleading.

21           Although the product would be sold to  
22 retailers, these types of claims would not appear on

1 retail ready packaging or those products sold  
2 directly to consumers.

3           To provide a little bit of background, I  
4 think it was also mentioned in the Federal Register  
5 notice, or alluded to in the notice, that N-60  
6 labels are intended to provide information to a  
7 receiving establishment about the supplier's HACCP  
8 system and the testing that that supplier does, in  
9 lieu of certificate of analysis, we recognize that  
10 these certificates of analysis are not being  
11 properly transferred with the products through  
12 distributors.

13           And we also want to be assured that the  
14 claim asserts that these raw beef components were  
15 produced under an integrated control program between  
16 the slaughter dressing operation and the trim  
17 production operations and that the product has been  
18 tested and that that testing was done by a  
19 particular sampling method.

20           Of course, in evaluating these types of  
21 label claims, there are specific conditions that  
22 need to be met. As with all labeling claims, the

1 labels need to be submitted for approval. This type  
2 of evaluation would be a little bit different than  
3 what we do in our traditional label evaluations. It  
4 would be more of like a technical review where we  
5 would have an ad hoc committee gather together  
6 technical experts from the Agency to review the  
7 information, and as I walk through what's included  
8 in the guidance, you'll see that there is quite a  
9 bit of documentation that should be submitted as  
10 part of the labeling application and that would be  
11 reviewed by this ad hoc committee.

12           As I said, the label submittal would have  
13 to include certain information besides the  
14 documentation. We would expect the label to also  
15 bear certain labeling information and, of course, we  
16 expect that our FSIS personnel will be developing  
17 instructions to verify that the claim is truthful  
18 when an establishment applies it to their labeling.

19           As far as what type of information would  
20 appear on the label, in addition to what is normally  
21 expected on a label that is applied to product at an  
22 establishment, a statement would need to be on the

1 label to convey that the testing was done by the  
2 establishment. Here's an example of something like  
3 derived only from ABC Company's N-60 Tested and  
4 Passed Beef Trim.

5           The label would also need to include a  
6 statement about whether the testing claim is  
7 specific to the label container or whether multiple  
8 containers are involved in a particular sample  
9 production lot. There's a couple of examples there,  
10 N-60 negative for 2,000 pounds, and as I said, this  
11 would not be expected on consumer size packages,  
12 consumer ready products. So also a statement of  
13 limited use, such as not for consumer labeled  
14 product.

15           The beef trim for N-60 tested products, and  
16 then various containers of tested trim, if they are  
17 mixed together to form a particular formulation, the  
18 N-60 label would also need to state that the final  
19 product was tested before it was combined with other  
20 tested trim, other tested trim that may bear an N-60  
21 label, but that that combination, that final product  
22 was not tested. If that final product was tested,

1 then the label could also state that as if N-60  
2 tested twice under a sampling program or any other  
3 appropriate qualification to convey that  
4 information.

5 In terms of documentation needed to support  
6 the label claim, of course, all the beef trim used  
7 to produce the product would have to originate from  
8 carcasses slaughtered at an official establishment  
9 with at least one validated intervention for *E. coli*  
10 O157:H7.

11 The documentation would also have to  
12 include that the N-60 tested claim would be  
13 supported by -- that the product was actually  
14 tested, and it could be either via a screen type  
15 method, using a FSIS method or an equivalent method  
16 for *E. coli* O157:H7 analysis, and then a statement  
17 in the HACCP plan that the testing was incorporated.

18 The sample collection methodology would  
19 also indicate that at least 60 randomly selected  
20 samples are analyzed and at least 325 grams of the  
21 product is composited and tested.

22 If any of the product tests positive, then

1 the documentation would also have to include that  
2 the lot represented by that sample was diverted from  
3 the ground beef operation. An example here is the  
4 positive lots are diverted to cooking or other  
5 further processing that will destroy the pathogen.

6 And then a description of that would need  
7 to be included by the establishment in the  
8 documentation that that property was properly  
9 disposed of.

10 There would also have to be evidence that  
11 there would be no re-sampling, no collecting of  
12 another N-60 sample of any production lot that tests  
13 positive.

14 If multiple operations within one  
15 establishment or multiple establishments are  
16 involved in creating the production lot for N-60  
17 tested trim, for example, if a slaughter processing  
18 operation establishment produces the trim, or the  
19 trim is derived from another establishment, which  
20 was also tested, or has a N-60 claim on it, then we  
21 would expect that the documentation would describe  
22 how the establishments communicate and how that

1 would be recorded regarding the slaughter/dressing  
2 performance and trim test results, how the would be  
3 made available to FSIS personnel for review at each  
4 establishment, and then how that information would  
5 be used to investigate and adjust the HACCP system  
6 to ensure that the system is adequate for control.

7           Additionally, a written protocol addressing  
8 the criteria used by the establishment requesting  
9 the approval of the N-60 label, to identify an  
10 acceptable number of sporadic positives from a trend  
11 towards a systemic failure to control *E. coli*, for  
12 example, those high event days, that this criteria  
13 would need to justify how to discern when one  
14 production lot is or isn't microbiologically  
15 independent of another when same source materials  
16 are used in individual production lots. That  
17 protocol would also have to describe the decision  
18 making for that product disposition. The lot  
19 represented by the N-60 sample has been diverted  
20 from the raw beef operation and then how this  
21 information would affect microbiological  
22 independents of a production lot.

1           The documentation would also have to  
2 include a description of how the approved label will  
3 identify the specific production lot that's tested.  
4 For example, through a lot code or a lot  
5 identification number.

6           As I said, we posted this draft guidance  
7 yesterday afternoon. It is indeed draft guidance  
8 for review and comment. So, of course, either today  
9 verbally or through written comments, we encourage  
10 you to submit it to the e-mail address I have there,  
11 and the comments will be accepted through November  
12 17, 2008.

13           Once we get the comments incorporated into  
14 some final guidance, then if we adopt the program or  
15 the Agency institutes this program, then we would  
16 suggest that you submit your label application, in  
17 the usual manner, those few that are familiar with  
18 that, it's also outlined in this website here, and  
19 we would evaluate whether or not the information  
20 that's submitted is enough to justify the product is  
21 labeled in a truthful and non-misleading manner.

22           I understand that because this review is a



1 little bit different than what we would do in normal  
2 situations of label kind evaluation, it may take a  
3 little bit longer, but we would, of course, try to  
4 expedite it in a way that would be acceptable to  
5 those establishments that are submitting for  
6 approval. Thank you.

7 (Applause.)

8 DR. ENGELJOHN: We have some microphones.  
9 I don't know where the microphones are. Okay.

10 MS. MURPHY-JENKINS: And as I said, because  
11 this is going to be a collaborative effort among  
12 Agency officials, in your questions today, either  
13 Dan or I will comment.

14 UNIDENTIFIED SPEAKER: This is just an  
15 observation. I know that it came up before that the  
16 perception and my perception also as having used the  
17 previous and the current FSIS methods, that the  
18 method has improved. When you say something that's  
19 been shown to be equivalent to the FSIS method, I  
20 would encourage you to actually say that it has to  
21 be equivalent to the current MLG method. A lot of  
22 things are in the marketplace, a lot of different

1 tests that were validated by AOAC or other agencies  
2 against methods previously in use by FSIS, not the  
3 method currently in use.

4           And I think in the interest of keeping  
5 quality up and making sure the testing is  
6 equivalent, that the MLG Guidebook version be  
7 specified.

8           MS. MURPHY-JENKINS: Thank you.

9           MS. ROSENBAUM: Donna Rosenbaum from STOP.  
10 I have a couple of comments.

11           First of all, I appreciate the opportunity  
12 to write in comments. I would like to request  
13 because of all of the detailed information that's  
14 going to go into comments that are meaningful, that  
15 you perhaps consider giving a couple of weeks  
16 additional time because I would personally like to  
17 have the transcript of this meeting to be able to  
18 prepare comments, and I've been taking notes but I  
19 can't write that fast, and there's a lot of things  
20 to think about in preparing these comments and we'd  
21 like to make them as meaningful as possible, and I'd  
22 like to see everybody in the consumer sector as well

1 as the industry sector be able to use the  
2 information that's coming out of this meeting  
3 informing very useful comments for you. So I think  
4 it would be very helpful to have that transportation  
5 before we got into that process. That's number one.

6           Number two, I would like to see also some  
7 definition in the sampling method. N-60 in and of  
8 itself when you just say N-60, as far as we're  
9 concerned, you know, it means different things to  
10 different people because it has so many variables  
11 involved in how it's applied, and N-60 in and of  
12 itself is not a sampling method. It just demands a  
13 certain number of samples being taken. So if you're  
14 going to do something based upon a label with  
15 something on it, I think you need to call it  
16 something more definitive than just N-60, so that it  
17 has a set plan behind it and a set number of points  
18 that everybody will know has to have been met to be  
19 able to call it that and have a label applied to it.

20           And in mind with the Safe Food Coalition  
21 comments that we gave yesterday, I personally, and I  
22 think the Safe Food Coalition, would be much more

1 comfortable with it being labeled as testing under a  
2 certified sampling plan versus specifically N-60  
3 because again, that might be subject to each plant  
4 and each process in each plant and it might not be  
5 appropriate. Different things might be appropriate  
6 for different plants.

7 MR. GOLTRY: Scott Goltry, AMI. I think,  
8 one, we appreciate the ability to comment on this  
9 and the draft guidance document, you said it was  
10 going to be coming and it's here, so we are able to  
11 comment on this N-60 labeling document which we  
12 appreciate that.

13 But I think also you need to understand or  
14 take a look at the risk of what is really being done  
15 now with not the ability to put labels on boxes that  
16 they have been tested to a N-60 or equivalent  
17 program, and how that's gone through the  
18 distribution system. Basically that information is  
19 being passed on through bills of lading or invoices  
20 to the first point of shipment and then from there  
21 on it's up to the brokers or distributors to pass  
22 that on to some of the small and very small

1 grinders.

2           Also I'd like to have you consider how  
3 product coming from Canada, trim that is destined to  
4 be ground down here would also fit under this kind  
5 of N-60 labeling or something equivalent like you  
6 mentioned, that would fit into that whole scenario.

7           I think it's a good idea that it is a  
8 voluntary situation or system, but to me I think  
9 there's a lot of like has been said earlier, there's  
10 a lot of devil in the details, and your risk group  
11 or whoever's going to be put to task to understand  
12 this situation, I think they need to understand that  
13 there's a lot of this information in here that's  
14 already being done and to have this great carrot to  
15 help the system identify what's N-60 and not N-60 I  
16 think could be problematic and over burdensome.

17           MS. MURPHY-JENKINS:   Maybe it pays to be  
18 34. Thank you. (Laughter.)

19           DR. ENGELJOHN:   This is Engeljohn. I did  
20 want to follow up. I did get one question earlier  
21 about whether or not the N-60 label could apply to  
22 the ground product, an operation that may, in fact,

1 be controlling product from slaughter to trim to  
2 ground, all the way through to the retail store but  
3 not to the consumer. And it's certainly is our  
4 intention to allow for that. So if you have some  
5 suggestions for how to incorporate a ground  
6 component onto this, we as well would find that to  
7 be something probably that would be of benefit to  
8 industry.

9           Again, the whole purpose here being to find  
10 a way to get at the issue of not having information  
11 transferred with product through the distribution  
12 channels. So if that's something that would be of  
13 value to industry, we certainly would entertain  
14 developing that further as well.

15           MS. JOHNSON:       Anything on the phone,  
16 Dr. Engeljohn? On the phone line.

17           OPERATOR:    If you'd like to ask a question,  
18 please press star and 1.

19                        (No response.)

20           OPERATOR:       At this time, I have no  
21 questions in queue.

22           DR. HOLLINGSWORTH:    Jill Hollingsworth,

1 FMI. Since this is a voluntary program, is there  
2 going to be any difference or significance or is  
3 FSIS going to address product that is labeled or is  
4 not labeled differently even though it may have gone  
5 through the exact same process? I guess I'm not  
6 clear on what will be distinctive about the product  
7 that is labeled if it's a voluntary label versus the  
8 product that is not labeled but may have gone  
9 through the same process, or is there any  
10 difference?

11 DR. ENGELJOHN: This is Engeljohn. I would  
12 respond by, I do see distinct differences between  
13 this and what's happening today and perhaps into the  
14 future, in that product produced under this system  
15 is one for which as Rosalyn mentioned in her  
16 presentation, is an integrated system whereby the  
17 Agency itself will be providing training and  
18 instruction to the FSIS employees in the plant to  
19 actually verify that the criteria is being met for  
20 the labeling claim program.

21 So there will be a specific focus on the  
22 actual interaction between the performance at

1 slaughter and the performance at trim, looking at  
2 the program to see that it is, in fact, being  
3 followed and those conditions being met. So that's  
4 a specific focus on a labeling claim process whereas  
5 today the inspectors are looking at a verification  
6 program for the system but not necessarily looking  
7 to verify that the pieces are tied together between  
8 the feedback between the slaughter and trim.

9           So we would view that as certainly being a  
10 more robust mechanism for the control. Again, it  
11 gets at the issue of feedback. It gets at the issue  
12 of us specifically verifying that activity and then  
13 the purchaser of product of who would be receiving  
14 this product would at least have additional  
15 information about the production process that is  
16 occurring at other establishments for which they may  
17 not be able to get as much information about the  
18 control program which is an argument that we've  
19 heard from particular the small and very small  
20 plants who feel they don't have the ability to get  
21 information about the production process, and  
22 certainly aren't able to get it on a routine basis



1 whereby today they may or may not get a certificate  
2 of analysis. They may or may not get information on  
3 the bill of lading, and they may or may not be able  
4 to get information from the processor about their  
5 production practices.

6           So we would certainly see it as a more  
7 robust mechanism for an integrated control in a more  
8 comprehensive food safety system. So we would see  
9 differences there and particularly for an  
10 establishment that was purchasing only this kind of  
11 product, labeled as such, would and could perhaps  
12 handle that product differently than one who doesn't  
13 have as much information.

14           MR. GOLTRY: A follow up, Scott Goltry,  
15 AMI. In your first bullet point, you mention that  
16 labels would be truthful, convey truthful and not  
17 misleading information.

18           MS. MURPHY-JENKINS: Uh-huh.

19           MR. GOLTRY: I think the intent of this  
20 label is to be truthful about was the product  
21 properly sampled for N-60 or another method,  
22 equivalent to that, and did the product test

1 negative and is the product in the box or container  
2 that product that was actually representing that  
3 sample. It sounds like we're going far above that  
4 to turn this into a total food safety evaluation and  
5 there are systems in place to already evaluate those  
6 food safety systems.

7 DR. ENGELJOHN: And I would just comment  
8 that again the issue at getting at more standardized  
9 approaches to this, one of the components and one of  
10 those bullets was that we're specifically looking at  
11 the decision making process within the plant on how  
12 they discern the difference between sporadic  
13 positives and those that could lead to evidence, the  
14 process is out of control, whereby they would  
15 control negative production lots differently on days  
16 in which they have that evidence. And that isn't  
17 something that's built into a very focused  
18 verification activity that we have today. So this  
19 would standardize that to a great extent across  
20 those plants that are using this label.

21 So we do see that it is a comprehensive  
22 look at the food safety system for which there's

1 feedback and we don't, we don't see the value in  
2 testing and not doing anything with that data. In  
3 fact, that's just a test and divert program that  
4 actually would not function as a mechanism to inform  
5 the system.

6 We believe this would provide greater  
7 control in place to get information back as to  
8 whether or not this system is working properly and  
9 is it adjusted appropriately.

10 MS. BUCK: This is Pat Buck from the Center  
11 for Foodborne Illness. Are we talking about a lot  
12 more resources to put this type of labeling in place  
13 not only for the Agency but also for the industry at  
14 large? Is this a serious resource problem?

15 DR. ENGELJOHN: From my perspective,  
16 Engeljohn's perspective about the design of the  
17 program and how it would be implemented is that, as  
18 I think Scott from AMI said, many of those in  
19 industry have programs in place that aren't as  
20 structured such that we, the Agency, are verifying  
21 them.

22 This would be a change in the inspection

1 procedure. So as we mentioned in one slide, it  
2 would entail a special training program whereby our  
3 inspectors in these plants would be provided  
4 instruction and training on how to verify this  
5 program. So that would be a change there.

6 I would see there would be an investment in  
7 training holistically across the board on this  
8 particular issue.

9 For those in industry, obviously it does  
10 change a bit from what they're doing. I would see  
11 that the reliance upon certificates of analyses and  
12 those quarterly follow ups or monthly follow ups  
13 that plants are doing today probably would not be as  
14 necessary. I think that's an intense activity that  
15 industry tries to comply with today but it isn't  
16 working well.

17 As far as resources in the Washington  
18 Office, we do have technical teams that we would be  
19 pulling together that would be reviewing this as the  
20 labels come in. So I think we've anticipated what  
21 we need to do. Our intention is not to have these  
22 applications for long periods of time. We recognize

1 there's a public health benefit in our opinion to  
2 this approach. So I think we would put the  
3 resources to it. We have the technical capability  
4 to do so.

5 I think the bigger issue though is if, in  
6 fact, we adopt a label along these lines, it is a  
7 matter of getting that information out, training on  
8 it, and then making sure that we're verifying  
9 appropriately.

10 There's, in the back.

11 DR. HARRIS: Joe Harris with Southwest Meat  
12 Association. Going along with Scott Goltry's  
13 comments a moment ago, it seems like that the  
14 current draft policy goes so far beyond what a  
15 current COA would include, that is it's a whole new  
16 program. It is not something that could be done in  
17 lieu of providing a COA. There are a lot of  
18 underlying things that would be implied by one small  
19 label statement, and I would be concerned that the  
20 usefulness of this is going to be extremely  
21 compromised by having so many strings attached to  
22 one small label statement that it's not going to be

1 worthwhile for processors to go through all of the  
2 things that they're going to have to go through for  
3 this label claim when a lot of the things they're  
4 already doing anyway. But now they're all being  
5 tied to a single labeling claim.

6 So we would caution that there is just too  
7 much being implied by one label statement.

8 DR. ENGELJOHN: I appreciate that. I will  
9 say again from the Dan Engeljohn policy perspective,  
10 the certificates of analyses today are of little  
11 value frankly in terms of how they're used and being  
12 used by industry. I think that in terms of reliance  
13 upon them and the information that they're intended  
14 to imply to the industry, particularly those who are  
15 purchasing the product is not as robust as it needs  
16 to be, and so I think today I think there is some  
17 evidence that it's a paper exercise which needs to  
18 be strengthened.

19 Are there any questions from the phone?

20 (No response.)

21 DR. ENGELJOHN: If not, I think we'll move  
22 to the next presentation.

1           MR. ALMANZA:       Our next presenter is  
2 Dr. Barbara Masters. Dr. Masters is a senior policy  
3 advisor at Olsson, Frank and Weeda. Before joining  
4 the firm, Dr. Masters served as Acting Administrator  
5 and then Administrator for USDA FSIS from March 2004  
6 through January 2007.

7           During her tenure as Administrator, she  
8 worked to establish -- no, she established a solid  
9 infrastructure of science-based policies and data  
10 analysis which have helped to reduce foodborne  
11 illness and product recalls. Dr. Masters.

12          DR. MASTERS:       Thank you, Mr. Almanza.  
13 Certainly I think this has been a good opportunity  
14 to have a lot of dialogue and discussion about *E.*  
15 *coli* O157:H7 and sampling and a lot of things that  
16 have been going on both with the industry and some  
17 of the training and some of the things that have  
18 been happening in FSIS.

19               I don't think I have anything new in my  
20 presentation, but I think what is unique and  
21 different about the presentation that I have is that  
22 it does relate specifically some learnings from 2007

1 and 2008.

2 I want to thank my colleague, Dennis  
3 Johnson, who assisted me in putting this together as  
4 well as some of those in industry who may or may not  
5 know they assisted in putting this together.

6 This presentation focuses on some specific  
7 illnesses. We know that in 2007, there was at least  
8 nine beef related outbreaks. We acknowledge there  
9 may have been more but CDC reported at least nine  
10 beef related outbreaks, five multistate outbreaks  
11 which we're going to focus on three.

12 And we're focusing on these three because  
13 we had specific information that we were able to  
14 obtain the data on particularly related to the  
15 source involved in these outbreaks related to the  
16 raw materials.

17 We also will acknowledge that the illness  
18 information is based on unofficial preliminary  
19 reports that may be incomplete.

20 So being consistent with how CDC would  
21 present this type of information, we're going to  
22 focus on Grinder A, B, and C, and Grinder A was



1 involved with 36 illnesses, B 47 illnesses and  
2 Grinder C, 52 illnesses. So clearly these were  
3 large outbreaks in 2007.

4 We had to, as we've talked all the last day  
5 and a half about assumptions, and you always have to  
6 rely on underlying assumptions. These outbreaks all  
7 were the result of grinding operations, and they  
8 were traced back to grinding operations, and the  
9 root cause, if we look at these grinding operations,  
10 we do not believe, we made the assumption that the  
11 grinding facility was not the root cause. Their  
12 practices were not the root cause per se, that they  
13 purchased product that was contaminated, and it was  
14 contaminated to a level such that it did lead to  
15 illnesses.

16 Certainly we heard some things over the  
17 last day and a half, 2007, was it anomaly? We  
18 talked about process control at the slaughter floor.  
19 That's where it all happens. So we are looking at  
20 the suppliers. Did they have process control  
21 levels? Dr. Engeljohn talked about clearly if  
22 you're exceeding your process control at a certain

1 level, all of a sudden your interventions aren't  
2 working anymore. So what happened that these  
3 suppliers in 2007 to these illnesses, we don't know,  
4 but we do know in these cases their products reached  
5 the grinders, and once it reached the grinders,  
6 there's basically virtually nothing the grinders can  
7 do.

8 Mr. Biela talked about, he had a program in  
9 his facility, cold chain management, looking at  
10 suppliers of incoming product, those kind of things,  
11 but once he gets the product, he has that product.

12 And so we're saying, our assumption is the  
13 inquiry should focus on the ultimate suppliers of  
14 that product. Those are our assumptions.

15 So let's walk through our individual  
16 grinders from 2007. Grinder A had many, many  
17 suppliers, but they had three common suppliers  
18 during that period of the outbreak. They had a  
19 Canadian slaughter establishment, and it's the only  
20 establishment that we're specifically naming. It's  
21 Rancher's, and we did that only because in follow up  
22 to this establishment, FSIS did ultimately publicly

1 acknowledge Rancher's had testing issues, a Western  
2 slaughter establishment and an establishment that  
3 was providing low temperature rendered product which  
4 I think Dr. Engeljohn mentioned was something one of  
5 the Advisory Committees had suggested FSIS needed to  
6 look at differently in some of their baseline  
7 testing.

8           We have Grinder B, who also had various  
9 suppliers but FSIS did indicate in that case the  
10 likely source was Rancher's Beef in Canada, and they  
11 did that in a press release.

12           And then we have Grinder C who also had a  
13 variety of suppliers but they had four that were  
14 common during that outbreak period. Southwest  
15 establishment, South American country, a Midwest  
16 establishment and then an establishment that was  
17 providing treated trimmings, trimmings that had a  
18 lethality step applied to them.

19           So what are some common themes when we  
20 trace back? We talked about tracing back to  
21 suppliers a lot in the last day and a half. What  
22 are some common themes when we then took this

1 information and looked back at the suppliers?

2 Well, interestingly, none of these  
3 suppliers that we looked at had a high incident rate  
4 for *E. coli* O157:H7 in their own trim testing. I  
5 certainly don't want to suggest that just because  
6 you don't have a high incident rate, that that's an  
7 automatic, oh, no. Certainly somebody could be  
8 doing everything right and not have a high incident  
9 rate but certainly that should raise questions about  
10 what's going on. We talked about feedback loops to  
11 the system. So that's just one piece of  
12 information.

13 Two slaughter establishments had  
14 questionable process controls, and I say that from  
15 the perspective that one of them had not properly  
16 validated the use of lactic acid for their carcass  
17 intervention step, and I would say to you that this  
18 particular slaughter establishment was only using  
19 lactic acid as their intervention for controlling  
20 O157:H7 on the slaughter floor, and they were using  
21 it at 1.5 percent. Most of the journal articles and  
22 research articles out there suggest using lactic

1 acid, if you're going to use it to control 0157, at  
2 at least 2 percent. And so this was the only  
3 intervention step they had on their slaughter floor,  
4 and they had not properly validated it.

5 Another establishment when you went back to  
6 look at their slaughter floor only was using hot  
7 water, which is a good intervention but they had not  
8 properly validated that on their slaughter floor.  
9 So questionable process control on slaughter floor.

10 Two of the establishments had questionable  
11 sampling practices. We talked about Rancher's.  
12 That's one of the suppliers at two establishments,  
13 and FSIS acknowledged that they were doing  
14 retesting. And one of the other establishments was  
15 not taking N-60 samples from the exterior slices  
16 which both Dr. Kelly and Ms. Rossman talked about.  
17 You absolutely have to take the exterior surface and  
18 that was verified by a third party audit when there  
19 was a follow up back at that particular slaughter  
20 establishment.

21 And only one of them said was using the  
22 treated trimmings, which is a positive finding, but

1 only one of them was doing that.

2           So that's the common theme of things that  
3 we have.

4           So we kind of summarized our learnings from  
5 2007 that the suppliers in these cases had extremely  
6 low trim incident rates. In fact, some of them had  
7 no positives, when the industry average, and we had  
8 to put that down there as something, based on the  
9 draft compliance guidelines that FSIS had put out,  
10 at 1 to 2 percent anecdotally. So they were down at  
11 0 or very low when the rest of the industry has had  
12 about 1 to 2 percent. That really 1 to 2 percent  
13 really is providing feedback to the slaughter floor,  
14 to the system.

15           So these establishments really didn't have  
16 that feedback loop to their system, which was  
17 allowing them to have deficiencies in their  
18 slaughter process, and again as we've talked in the  
19 last day and a half, your process control begins on  
20 the slaughter floor. That's where you're going to  
21 control *E. coli* 0157.

22           So we move to 2008. Obviously there's been

1 multiple outbreaks in 2008, but there's really been  
2 three outbreaks in 2008. Retailer A, Retailer B and  
3 then the non-profit organization. The source for  
4 the non-profit organization has not really been  
5 conclusively demonstrated for that outbreak. So  
6 we're really not going to discuss it further here.  
7 We're going to focus on Retailer A and Retailer B.

8           Retailer A and Retailer B had a common  
9 supplier. We're going to call it slaughter  
10 establishment A, and I have to acknowledge, I don't  
11 have firsthand information for slaughter  
12 establishment A, and it's based on third party  
13 information. So if it's not 100 percent accurate,  
14 you know, when you're relying, when you're going to  
15 third party, it gets a little bit further removed.  
16 So I will state that up front, but what we have  
17 heard from third party information is that this  
18 slaughter establishment did not have any positive  
19 trim findings in 2007 or 2008 before these  
20 outbreaks. So again, none of their own  
21 establishment positives.

22           What we do know from the recently published

1 National Trim Baseline is that they did have  
2 positive findings in the FSIS Trim Baseline.

3 We have heard that their analytical sample  
4 size was 25 grams. We know the industry standard is  
5 375 grams, and Dr. Esteban shared that the FSIS  
6 sample size is 325 grams. So we're looking at a  
7 different sample size used by this establishment.

8 And we have heard that customers who  
9 conducted testing on this establishment's product  
10 detected multiple positives when they acquired the  
11 product from this establishment.

12 We also have heard that for production at  
13 issue in the outbreaks, that this establishment made  
14 a decision to not operate all of their  
15 interventions.

16 So we would suggest that the learnings in  
17 2008 are the same as that in 2007, that you have a  
18 supplier, again a supplier, that had no positives in  
19 their own trim testing when the industry as an  
20 average gets about 1 to 2 percent to use as their  
21 feedback loop. So this supplier, the slaughter  
22 establishment, did not have their feedback to their



1 system to detect what was going on or to use as  
2 feedback to their slaughter process. So again, you  
3 would begin to question what's happening in their  
4 slaughter process.

5           So how can you apply these learnings?  
6 We're not suggesting that testing should be  
7 mandatory, but if establishments are going to rely  
8 on sampling as feedback to their slaughter process,  
9 and again we would suggest it's a good thing to do,  
10 that that testing needs to be done in a way that it  
11 can, in fact, provide feedback to your system  
12 because as we've heard over and over again, that's  
13 where your process control has to begin. You need  
14 process control throughout the process, but it  
15 certainly needs to begin at the slaughter floor.

16           But for your sampling to be meaningful,  
17 whether you get negative results or positive  
18 results, you need proper sampling and laboratory  
19 techniques.

20           I don't want to suggest that a lot of  
21 positive findings don't have one meaning or that  
22 just because you get positives you should be

1 penalized, that positive results you need proper  
2 sampling and laboratory techniques, and you need  
3 that for negative results. It's equally important  
4 regardless of your sampling.

5           But I would suggest that in our case, what  
6 we found from our learning is that, in particular, a  
7 virtual absence of positives should clearly trigger  
8 a review as to the adequacy of sampling and/or  
9 laboratory results. Again, I think there are  
10 establishments out there that have clearly worked on  
11 their process enough that they do get a period of  
12 time for which they get no findings, but I think  
13 they would welcome a rigorous review of their  
14 process.

15           I think that should entail, is the sample  
16 being collected properly? Is it a surface excision?  
17 Are they getting a 375-gram sample or a 325-gram  
18 sample? Is it being properly enriched? Is the  
19 laboratory method adequate to detect all of the *E.*  
20 *coli*? Is it as sensitive as the FSIS method? And I  
21 agree, it's a good point that this gentleman made  
22 over here. We do mean the current MLG method.

1           Dr. Danielson mentioned recently that FSIS  
2 came in and looked at his laboratory methods and  
3 found a discrepancy. I think that's what we're  
4 talking about here. What is happening from a  
5 sampling perspective, and if somebody's getting all  
6 negatives, that should be a meaningful all negative.  
7 It doesn't mean it's wrong, but is it a meaningful  
8 all negative?

9           We would suggest for FSIS, we had access to  
10 data for a few of the outbreaks in 2007 and got some  
11 third party information for 2008, and we would  
12 encourage FSIS to go back to all of the outbreaks  
13 for 2007 and 2008 and look at all of the suppliers.  
14 Look at the HACCP records and the *E. coli* test  
15 results during the relevant period of the outbreak  
16 and focus particularly on those establishments that  
17 had all negative findings. We would anticipate  
18 there may be other plants that had all negative  
19 findings during those outbreak periods.

20           What was happening with their interventions  
21 on the slaughter floor? Were they operated as  
22 intended? For example, if they were using something

1 out of the FSIS Directive 7120.1, which is the  
2 directive that defines antimicrobials for example,  
3 were they using that as it's described or was it  
4 validated if they were using something different?  
5 We would encourage FSIS to go back and look at the  
6 sample methods. Obviously they can't go back to  
7 2007 and see how they were sampling then, but  
8 certainly they could verify how those facilities are  
9 sampling now.

10 I have been in facilities in the last year  
11 and a half I can tell you. Not everybody does a  
12 good N-60 method. They should look at the  
13 laboratory method and ensure that they're using a  
14 laboratory method. They should have records for  
15 what they were using then. Was it a method that's a  
16 sensitive as FSIS and what are they using today?

17 Because again, our hypothesis is that  
18 process control at slaughter is essential to control  
19 *E. coli* O157:H7. Effective process control is based  
20 on validation of the process as well as ongoing  
21 verification. It takes both, and if an  
22 establishment is going to use testing as part of

1 their ongoing verification, that testing must  
2 incorporate adequate sampling and analytical  
3 techniques.

4 And if that's true, then we would suggest  
5 FSIS must adopt policies to address this, to  
6 minimize future outbreaks.

7 FSIS should emphasize at slaughter  
8 operations that serve as a source to the grinding  
9 operations. They should look at the validation of  
10 programs, the on-going verification, surface  
11 excision, and I think they've started to do that.  
12 You heard Dr. Kelly talk about her regulatory  
13 education program. What did they learn through  
14 their 65-07 and have they addressed all of that? If  
15 you read the 65-07 and what they found in their  
16 review, it was a lot of very small facilities, and  
17 so certainly Dr. Kelly talked about what she's doing  
18 for the small and very small plants on sampling, but  
19 what did they find from a verification and from a  
20 validation perspective, and are they ensuring that  
21 they're getting that information out to the small  
22 and very small plants and to their inspection

1 personnel to ensure that they had adequate in to  
2 make sure these kind of things are happening. I  
3 appreciate the perspective that Dr. Kelly and  
4 Ms. Rossman are working together to get the BIFSCO  
5 documents out there and to get the training  
6 materials out there, but if we don't get this  
7 information out there, we are selling ourselves  
8 short to make sure we are fixing some of the issues  
9 that we learned at least in the few outbreaks we  
10 followed up on to make sure we're not preventing  
11 future outbreaks.

12           We would also encourage FSIS to focus on  
13 trim testing rather than ground testing to test  
14 closer to the source. From our perspective, that  
15 actually eliminates that need for trace back. We  
16 talked about trace back. If you actually test the  
17 trim product, you are testing where the trace back  
18 would occur. So there is no need for trace back,  
19 and we would encourage FSIS to consider additional  
20 trim testing, and Dr. Esteban talked about the  
21 difficulty in getting some trim samples, but he also  
22 talked about FSIS' exploring new methods to ensure

1 they can better trim samples, and we would encourage  
2 that to continue so that they can get better trim  
3 samples at the laboratory and make sure that they're  
4 following through on that because then you eliminate  
5 that need for the trace backs.

6           So those are some of the things we would  
7 encourage based on our learnings, and if FSIS is  
8 able to follow up on the other outbreaks and get  
9 consistent answers, then we believe that that may  
10 assist them in moving forward with some of their  
11 direction. Thank you very much.

12           (Applause.)

13           DR. ENGELJOHN: Questions?

14           MS. NESTOR: Felicia Nestor, Food and Water  
15 Watch. That was great, Dr. Masters. That's a very  
16 encouraging presentation. I have a couple of  
17 questions, and maybe this is for Dan.

18           The issue about deciding not to operate all  
19 interventions. If you had a HACCP plan, doesn't it  
20 specify how many interventions you use, and if you  
21 don't use all of them, you have not used your HACCP  
22 plan or can a person set up a HACCP plan that says,

1 you know, I may use any or all of these three  
2 interventions, and that would be one HACCP plan, and  
3 they would have the discretion during the process  
4 to --

5 DR. ENGELJOHN: This is Engeljohn. A  
6 properly validated system would have one for which  
7 they would know what the individual contribution is  
8 for the hurdles that they would have in place, and  
9 they would know that and they could adjust their  
10 system accordingly based on the consumer  
11 preferences. In this particular case, as an  
12 example, for natural or a process for which certain  
13 application of chemicals might not have wanted to be  
14 applied to the products, the customer may have  
15 requested that. In those kind of cases, we would  
16 expect that to have been validated.

17 So it's an issue for which a properly  
18 validated system would have addressed and would have  
19 known what the vulnerability would be for producing  
20 product that might get through the system in terms  
21 of O157.

22 MS. NESTOR: Okay. The only thing I just



1 want to make a comment that I mean this seems to  
2 suggest exactly what the consumers were advocating  
3 yesterday, which was a lot more information about  
4 where the contamination is in the grinding plants,  
5 you know, where it's coming from, which suppliers  
6 it's coming from. And I also would definitely agree  
7 with the recommendation of additional trim sampling  
8 for the same reason, because you're closer to the  
9 supplier and you can start identifying the problems.

10 DR. ENGELJOHN: I will just address that  
11 one particular issue on the trim sampling, and it's  
12 one for which we, the Agency, recognized that we  
13 needed to do. We began that program a year ago  
14 March. So it's now a year and a half or so old in  
15 terms of a program that we think added value to our  
16 overall determinations about the adequacy of the  
17 systems.

18 What's important to the Agency now is to  
19 look to make sure that we get in the number of  
20 samples that we actually schedule.

21 Because we have a baseline positive rate  
22 that we work from, the trim sampling program is one

1 for which we actually determine how many samples  
2 should we pull, based on the fact that we were  
3 looking for being able to measure a statistical  
4 difference in the positive rate. And so we were  
5 able to do that because we had a baseline value.

6           So the focus I think as we go forward,  
7 first of all, is to make sure we get the number of  
8 samples that we schedule, the number that we  
9 schedule is 3742 in a year. And so the question  
10 becomes are we getting that and making sure that we  
11 do, and then as recommended by Dr. Masters, is  
12 should we consider reallocating or perhaps adding  
13 resources to add more samples to get a better  
14 perspective about that, and I think those are the  
15 kinds of things that we certainly welcome your input  
16 on from everyone out there, but it is something that  
17 we are actively looking at as well.

18           MS. NESTOR: And I'm sorry, I do have one  
19 other question. Dr. Masters, can you explain again  
20 what you mean about common suppliers for your 2007?  
21 You said that these were the common suppliers, but  
22 there were additional suppliers during a certain

1 period?

2 DR. MASTERS: Yes.

3 MS. NESTOR: Are you saying that -- were  
4 these outbreaks a result of more than one lot of  
5 product, the result of production over a number of  
6 days?

7 DR. MASTERS: No. When you look at -- what  
8 you have to do when you start looking at an  
9 outbreak, you have to go then and see how many  
10 suppliers, these companies, these grinders supplied,  
11 had. So they might have had -- let's say they had  
12 10 suppliers. Then you have to say what suppliers  
13 actually supplied the production during the period  
14 for which the outbreak occurred. Then you have to  
15 start looking at the common suppliers. You have to  
16 start narrowing your window down to the common  
17 suppliers that supplied during the period of the  
18 outbreak. And so then you have to narrow it down to  
19 see which suppliers were involved during the period  
20 of the outbreak. And so these were the ones that  
21 actually supplied during the period of the outbreak  
22 and the recall.

1 MS. NESTOR: Are you saying they were the  
2 only ones that supplied during that period of they  
3 were the ones that were common throughout the  
4 period?

5 DR. MASTERS: Okay. So Felicia's asking  
6 about the common suppliers, and so these grinders  
7 obviously have multiple suppliers, and then you go  
8 back to the recall and you see how many were  
9 involved in the recall and the outbreak, and you  
10 have to go back and narrow it down to common  
11 suppliers during the recall and the outbreak. And  
12 so they have multiple suppliers, but these were the  
13 common suppliers during the days of the recall and  
14 the outbreak event.

15 MS. ROSENBAUM: Donna Rosenbaum from STOP.  
16 This is a comment basically on your presentation,  
17 more for the Agency, in terms of I think we agree  
18 that, you know, more sampling is great, but you have  
19 a dichotomy here between sampling and then processes  
20 that when failed indicate HACCP failures, and I'm  
21 concerned. I see value in going back and looking at  
22 what went wrong in all those outbreaks in 2007 and

1 2008. What concerns me as a consumer is that we  
2 don't have more preventive, real time evaluation  
3 going on continuously that would prevent, be more  
4 preventative in nature than going back a year and  
5 half after something happened or two years after it  
6 happened and saying what could we have done better  
7 here. These themes and these HACCP failures should  
8 have been evident to the Agency at the time they  
9 happened and I think the Agency needs to look at why  
10 that didn't happen and then move forward with  
11 getting more towards a real time evaluation of those  
12 events.

13 DR. ENGELJOHN: There's a question here.

14 MS. KOWALCYK: Barb Kowalcyk, CFI. It's  
15 more of a comment. Barbara, I really enjoyed your  
16 presentation. I guess enjoy is probably not the  
17 right term, but I think it certainly emphasizes the  
18 need for movement towards consistent sampling and  
19 the need to put statistics back into statistical  
20 process control as we've been discussing for the  
21 past couple of days.

22 And I think one point that you made that I

1 want the Agency to take particular note of is this  
2 whole idea that a virtual absence of positives tells  
3 you something. It tells you one or two things.  
4 Either their sampling plan is inappropriate and  
5 they're not catching contamination that's there or  
6 two, they've discovered some really remarkable  
7 intervention that has improved the process that  
8 much. Either way, you need to look into it, and it  
9 should flag something to both the plant and to FSIS  
10 that there may be a potential problem. You would  
11 not expect to go that long without having a positive  
12 in that situation. I just want to reiterate that  
13 point and I want to reiterate what Felicia said.  
14 This certainly provides justification for the things  
15 that the consumer groups have been asking for and  
16 that plants need to develop reliable, robust  
17 sampling plants that are implemented correctly and  
18 then use that data to draw accurate generalizations  
19 about the population so that we can prevent illness.  
20 As Donna said, we don't really want to find out a  
21 year and a half afterwards. If this is done  
22 continually, you would have caught this in the

1 process rather than after people have gotten sick.

2 MS. BUCK: Hello, this is Pat Buck from  
3 CFI. And I looked at your recommendations and I'm  
4 trying to piece this together in my mind. Is this  
5 something where you feel labeling for N-60 would be  
6 helpful?

7 DR. MASTERS: The question on the table is,  
8 is this something where I feel labeling for N-60  
9 would helpful?

10 I think labeling for N-60 is a tool, and I  
11 don't think labeling for N-60 is really necessarily  
12 related to what we're talking about here. This is  
13 Barb -- as Dr. Engeljohn said, this is Dan Engeljohn  
14 from policy. This is Barb Masters. I personally  
15 believe FSIS already has the authority to verify  
16 what they're asking for in the program related to  
17 the N-60, and so I would suggest they're already  
18 able to verify the things related to N-60 label.  
19 And so I would suggest that the N-60 labeling is  
20 just a tool, and FSIS already has the ability and  
21 should, in fact, be verifying a lot of things that  
22 they're asking for around that labeling.

1           And so I'm not sure that there's added  
2 value to that label. It kind of gets back to  
3 Dr. Hollingsworth's question. Is there value added?  
4 If FSIS was already verifying those programs around  
5 that label, as I believe they have the authority to  
6 do, then I think the N-60 label could be a tool and  
7 is not necessarily an added tool. It's just a tool  
8 that people could choose to use. But again that's  
9 my personal perspective.

10           DR. HOLLINGSWORTH:       Jill Hollingsworth,  
11 FMI. Thanks, Dr. Masters, for this information. I  
12 thought your retailer example was interesting since  
13 actually there were three retailers involved in  
14 these recalls. But one of the bullets you had on  
15 the retailer recalls was that the customers who  
16 conducted testing on establishment A's product  
17 determined multiple positives. And I'm curious as  
18 to what happened with those results. I mean, given  
19 that that product itself probably was diverted by  
20 the grinding operation, but was there anything done?  
21 Obviously the customer receiving this product knew  
22 something was amiss if they were getting that many



1 positive products, and is there any requirement that  
2 something be done? Is there any notification  
3 procedure? What should have or did not happen as a  
4 result of these customers finding all of these  
5 positives coming to them.

6 DR. MASTERS: Dan, do you want to --

7 DR. ENGELJOHN: This is Engeljohn. In this  
8 particular situation, of course, a part of this was  
9 a consequence of the investigation as to what  
10 happened. So it's part of how we find out these  
11 things. Part of the issue though is for the Agency  
12 to have access to information for which the plant is  
13 making determinations about various programs.

14 And so I would just respond by saying in  
15 this particular case, an investigation is what  
16 uncovered what we ultimately found out. The reality  
17 is that if, in fact, those lab results were  
18 affecting the food safety system, those would be the  
19 kind of records that we would expect to be on file  
20 at the establishment for which the inspectors would  
21 have access to and that they would be responding to  
22 in terms of asking questions about it.

1           There is a requirement for the inspectors  
2 to meet on a weekly basis with plant management to  
3 review testing results and to ask questions or to  
4 get further information. And so the process would  
5 have been if this had triggered changes in the  
6 program, then that should have been part of the  
7 overall food safety system. But it was discovered  
8 through an investigation.

9           MS. NESTOR: Felicia Nestor. I have a  
10 follow-up to that. Are the inspectors instructed  
11 once they have that work unit meeting to notify the  
12 D.C. office that the plant where they're working  
13 found a positive on X supplier plant's product?

14           DR. ENGELJOHN: This is Engeljohn. The  
15 expectation for the inspectors is that when they  
16 have questions or concerns about the data that they  
17 have, they may not be capable of determining the  
18 merit of the information but through their  
19 supervisory chain should, in fact, take steps to get  
20 answers. So the process would be that. There isn't  
21 a requirement today as we have discussed over the  
22 last day and a half, that individual establishment

1 data from another plant is actually informing the  
2 system. So our inspectors in a plant know what  
3 happens in that plant, not necessarily what's  
4 happening in another plant.

5 MS. NESTOR: So then USDA doesn't really  
6 have the ability to learn that two different  
7 grinders in two different parts of the country had a  
8 positive with a certain supplier?

9 DR. ENGELJOHN: This is Engeljohn. I would  
10 respond by saying that that may be the case today  
11 if, in fact, that information isn't made part of the  
12 food safety system at the establishment where that  
13 record would be reviewed. It's certainly an area  
14 for which we know we need to find some mechanism to  
15 address.

16 Are there any questions on the phone,  
17 Operator?

18 OPERATOR: Once again, if you would like to  
19 ask a question from the phone, please press star and  
20 1.

21 (No response.)

22 DR. DANIELSON: Good information, and for

1 all of us in this business, that kind of information  
2 is valuable on lots of issues. If there was some  
3 type of opportunity that the Agency or however could  
4 share case studies with us more quickly than when  
5 they're occurring, we, every time we get this  
6 information, go back and look within ourselves and  
7 it helps. I mean if we have gaps, we need to fix  
8 them. If we don't know about them, we can't address  
9 them, and whether it's us or them or whomever, case  
10 studies of, you know, you've got the epidemiology  
11 associations to the outbreaks to the trace backs. I  
12 know there's a lot of confidential information  
13 involved, and it's a difficult process, but it's  
14 very valid information for all of us to push process  
15 improvements.

16 DR. ENGELJOHN: This is Engeljohn, and I  
17 would say we agree, and it is another area where we  
18 know we can improve and find a mechanism to get  
19 information out quickly.

20 DR. MASTERS: Thank you.

21 DR. ENGELJOHN: Thank you, Barb.

22 (Applause.)

1           MR. ALMANZA:   Okay.   Well, that's the end  
2 of the presentations.   So we're going to open it up  
3 for any comments that anyone may have to end the  
4 meeting.

5           MS. NESTOR:   Felicia Nestor, Food and Water  
6 Watch.   I have a question about a number of comments  
7 that have been made.   It seems like a number of  
8 people are saying that you're more likely to find  
9 the pathogen on the external tissue which is the  
10 fatty trimmings, but if I'm not mistaken,  
11 Dr. Esteban, didn't you say yesterday that you found  
12 that it's more recoverable on the lean trimmings, so  
13 we've got this sort of paradoxical thing that you  
14 find it one place but you can't detect -- you're  
15 more likely to detect it at a place you don't  
16 normally find it?

17           DR. ESTEBAN:   You're right.   The current  
18 method detects a little bit less effectively or  
19 efficiently on fatty tissue than non-fatty tissue  
20 but it still has the ability to pick it up at very,  
21 very low levels.   So it's not that it doesn't work,  
22 it doesn't work as nicely as it works with lean

1 meat. So again it's something we could improve on,  
2 but I think it's fit for the purpose right now.

3 DR. ENGELJOHN: Felicia, I did just want to  
4 follow up, and again I think it gets back at looking  
5 at our training materials and looking to see what  
6 our inspectors are doing. We don't know or at least  
7 I would say in the Policy Office, I don't yet know  
8 whether or not we are focused at only pulling trim  
9 samples or are focused on pulling fat samples. I  
10 know from the type of samples coming into the lab,  
11 you saw the variation that Dr. Esteban provided  
12 yesterday. It's an area for which we need to look  
13 at.

14 For us though, the most important thing is  
15 making sure we're getting the right tissue which is  
16 the exterior, exposed tissue to that contamination.  
17 So there is a need for us to look to see what's  
18 being done and to better standardize that amongst  
19 our employees.

20 MS. NESTOR: Okay. I have one other  
21 question, and this is about the compliance  
22 guidelines, the draft, and I don't have it in front

1 of me, but it seems to me that what is suggested in  
2 that document is that the Agency recognizes that N-  
3 60 is not sufficient to use for disposition on one  
4 lot of product because it doesn't give you a 95  
5 percent confidence when there's not a 5 percent  
6 prevalence. But that if you were using N-60 in the  
7 context of process control, where you're going to  
8 have multiple lots tested, it can be reliable to  
9 tell you when your process is out of control. Do I  
10 have that right?

11 DR. ENGELJOHN: This is Engeljohn. I would  
12 agree with that concept. We think it should be an  
13 integrated system that involves more than just 0157  
14 testing. 0157 testing is a mechanism to look at to  
15 see if 0157 is there in the sample lot that you're  
16 looking at. We find N-60 to be a practical  
17 mechanism to do so and have accepted that. We think  
18 it can be vastly improved upon, but just reliance  
19 upon 0157 is not sufficient. There should be other  
20 process control indicators demonstrating that the  
21 system is working properly and 0157 should be one of  
22 those mechanisms to provide you additional feedback.

1 MS. NESTOR: So for the very small plants  
2 that are now strongly encouraged to do N-60  
3 sampling, should they anticipate that coming down  
4 the pike is a guideline or recommendation that their  
5 use of N-60 on single lots of product is  
6 insufficient?

7 DR. ENGELJOHN: Well, again the guidance  
8 that we did provide to very small plants and  
9 particularly small and very small production volume  
10 plants was that for those operations that are  
11 purchasing materials, there is an expectation that  
12 that would have been pretested. So that provides  
13 one additional means by which they could choose to  
14 at least procure products that has an added value to  
15 it.

16 For those operations that are slaughtering  
17 the individual cow and dismantling it over time,  
18 well, there are other mechanisms that those  
19 operations can have in place. One is the process  
20 control that they have on their slaughter/dressing  
21 operations. We see value in having microbiological  
22 tests to demonstrate process control and we talked



1 about indicator organisms, indicators for the  
2 process, and we see value in O157 testing as a means  
3 to also demonstrate that over time, their system is  
4 controlling at an adequate level.

5           So we look at it holistically using the  
6 historic data, over time that your process is  
7 presenting what you intend it to present. That's  
8 how we would look at it. If the issue is, and we  
9 work with, in particular, the organizations involved  
10 with small and very small plants to try to get  
11 better guidance out there. They have presented us  
12 with some scenarios to specifically address, to try  
13 to get better, more specific information and that  
14 would be something that we intend to do very shortly  
15 in terms of making that information available.

16           We would welcome any input that you think  
17 we need to give to small and very small plants to  
18 help them with practical ways to demonstrate their  
19 processes or controls.

20           MS. NESTOR: Yes, actually I can think of  
21 one now. I've talked to a number of extension  
22 agents around the country, and a number of them

1 complain that they don't get the -- you were talking  
2 earlier today about, you know, post-dating the  
3 effective dates so that there can be training and  
4 people get up to speed. A number of them complained  
5 that they are not forewarned about a lot of these  
6 things, and then they just get plants calling them  
7 up and they really -- they have to learn while  
8 they're trying to help these plants that are  
9 undergoing FSAs.

10 DR. ENGELJOHN: I see Karlease taking  
11 notes, and she'll address the issue. How we can use  
12 our partners out there to better get information to  
13 them in advance to prepare them and perhaps work  
14 with them in a better way. So we'll take that.

15 MR. ALMANZA: Any more?

16 UNIDENTIFIED SPEAKER: Yes, this is just a  
17 rather short question. I'm very encouraged by all  
18 of the discussions today, but one thing that I'm  
19 wondering about, in particular as I listened to Barb  
20 Masters', you know, presentation, how are we going  
21 to adequately address the product tracing issues  
22 that are, you know, before us as we try and figure

1 out what to do with as a response to contaminated  
2 product? Is FSIS considering holding a public  
3 meeting to look at these product tracing issues?

4 MR. ALMANZA: We don't have that -- we  
5 don't have plans for it as of yet, but certainly  
6 we've committed to having public meetings to address  
7 these types of issues. So --

8 UNIDENTIFIED SPEAKER: Because I think, I  
9 think product tracing is intricately, you know, tied  
10 to the issues that we've discussed here, and I would  
11 highly recommend that you follow through on product  
12 tracing. Thank you.

13 MR. ALMANZA: Thank you. Any other  
14 questions? Barb.

15 MS. KOWALCYK: Barb Kowalcyk, CFI, and it's  
16 just really a comment, and I think that one thing  
17 that's important to remember, and I'm very happy, I  
18 can't state it enough, I'm very happy with the  
19 direction the Agency is going. I think it needs to  
20 be flushed out more. I think there needs to be some  
21 things that need to be clarified, but I do think  
22 statistical process control will lead us out of

1 this, but one thing that's important for everybody  
2 to realize, is that SPC is really about controlling  
3 variation and you cannot -- SPC cannot overcome a  
4 poor process, and I think the thing that struck me  
5 the most about Dr. Masters' presentation is that  
6 that one supplier in particular had a poor process,  
7 and I think it's important to realize that there is  
8 a distinction between the two. Donna touched on  
9 this, too. You know, you have the whole HACCP plan  
10 which outlines the process, and then you have  
11 statistical process control which will monitor the  
12 process, and if you have a poorly designed process,  
13 you cannot overcome that. Similarly, if you have a  
14 poorly designed sampling plan, you cannot overcome  
15 that. The data has been flawed and you really are  
16 not going to be able to determine -- you're really  
17 not going to be able to meet the objectives then of  
18 the microbiological testing programs.

19           So I think that those are two important  
20 points that the Agency really needs to understand  
21 and clarify in its documentation. Thank you.

22           MR. ALMANZA:           Thank you.           Any other

1 questions?

2 (No response.)

3 MR. ALMANZA: Okay. Then we'll close the  
4 comment part.

5 I certainly appreciate all the comments.  
6 We heard a lot of -- we have a lot of good  
7 information, and I think that as I said yesterday,  
8 this is one of those processes that is difficult but  
9 we need to go through them in order to be open and  
10 transparent as we've committed to doing, and to  
11 understand that there are different stakeholders and  
12 different viewpoints and taking all of those into  
13 account and trying to do or trying to move forward  
14 with the Agency, I'm certainly encouraged by a  
15 couple of comments that they see the Agency going in  
16 the right direction. But we're not finished. I  
17 mean this is just kind of the beginning, and  
18 certainly we appreciate all of the comments and  
19 information we were privy to over the last two days.

20 With that, Dr. -- or Dr., I almost promoted  
21 you. Our new Under Secretary -- Acting Under  
22 Secretary Beth Johnson.

1 MS. JOHNSON: Thanks, Dr. Almanza. I know  
2 who's making the decisions here. So --

3 Well, I really want to thank you guys, and  
4 I appreciate the fact that you've taken so much time  
5 out of your busy schedules to provide us with your  
6 comments and your insights and your thoughts over  
7 this last day and a half. I know that I haven't  
8 been here for much of it, but I did get updates from  
9 Al and from others and it sounds like it's been a  
10 very productive couple of days. So again I thank  
11 you very, very much.

12 *E. coli* has certainly been a challenge over  
13 the last year and as most of us know, over a very  
14 long period of time. I've been with the Agency  
15 almost seven years, and much of that time has been  
16 spent on monitoring, looking, asking questions, and  
17 focusing on what we can do more to control this  
18 pathogen.

19 Certainly these public meetings, too, are  
20 very important in the process. They provide us with  
21 a lot of great information, a lot of outside of the  
22 box thinking, that unfortunately those of you know

1 that, both inside and outside of Government know  
2 it's easy to get caught up in what's going on in  
3 those four walls and it's great to hear from you  
4 guys and hear what your thoughts are.

5           And we've had a few public meetings over  
6 the last month, one to discuss low dose irradiation  
7 and also some summits that we've had, and so those  
8 of you that have been here to comment, we really  
9 greatly appreciate that.

10           Controlling *E. coli*, like I said, is a very  
11 important public health concern, but it's also a  
12 very complex issue, and we all know that no one  
13 meeting is going to address all the concerns and all  
14 the aspects of this problem, and from the important  
15 discussion at this meeting today, we want to  
16 identify other priority issues and to develop a  
17 series of public meetings over the next year that we  
18 can take to further the discussion and also more  
19 importantly is to look at how we can take actions to  
20 move this forward.

21           Obviously the discussion is very, very  
22 important. We need this. We want to be transparent

1 and open. We also know that discussion doesn't get  
2 the job done and so we are looking to continue to  
3 work with you to do that as well.

4           Some of you know that, like I said, over  
5 the last seven years, I've been committed to working  
6 on food safety for the Secretary of Agriculture.  
7 I'm also a parent, and I have two young children,  
8 five and eight, and so this is not only an issue  
9 that I look at from a professional standpoint, but I  
10 also look at it from a very personal standpoint.  
11 And I certainly agree with all the efforts that  
12 folks both at FSIS and in the Agency, who take this  
13 very, very seriously to protect ourselves and our  
14 children and our nation, that you all, too, are very  
15 committed to reducing our risk of exposure to *E.*  
16 *coli*.

17           I want to thank you again for coming out to  
18 this meeting and for any of you that attended the  
19 raising claims, natural raising claims meeting  
20 yesterday morning, you've put a lot of time into  
21 helping us move forward with our policies and our  
22 regulations, and so again I thank you very much and



1 look forward to continued dialogue as we move  
2 forward on these important issues. Thanks.

3 (Applause.)

4 (Whereupon, at 1:45 p.m., the meeting was  
5 concluded.)

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## 1 C E R T I F I C A T E

2 This is to certify that the attached proceedings in  
3 the matter of:

4 UNITED STATES DEPARTMENT OF AGRICULTURE

5 FOOD SAFETY AND INSPECTION SERVICE

6 ADDRESSING SAMPLING AND TESTING

7 METHODOLOGIES, COMPLIANCE GUIDELINES

8 AND N-60 LABELING

9 Washington, D.C.

10 October 15, 2008

11 were held as herein appears, and that this is the  
12 original transcription thereof for the files of the  
13 United States Department of Agriculture, Food Safety  
14 and Inspection Service.

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TIMOTHY J. ATKINSON, JR., Reporter

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